IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
	:	MDL NO. 2804
	:	
	:	
APPLIES TO ALL CASES	:	NO.
	:	1:17-MD-2804

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

December 7, 2018

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Videotaped sworn deposition of RICHARD J. FANELLI, Ph.D. (FACT), taken pursuant to notice, was held at DECHERT, LLP, 1095 6th Avenue, New York, New York, beginning at 1:02 p.m., on the above date, before Margaret M. Reihl, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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THE VIDEOGRAPHER: All right. The time is 1:02 p.m. We are on the record. Will the court reporter please administer the oath to the witness.

... RICHARD J. FANELLI, Ph.D., having been duly sworn as a witness, was examined and testified as follows:

MR. SNAPP: Could I just make a statement for the record and confirm that everyone in the room and on the phone agrees to be bound by the MDL confidentiality protective order or the confidentiality protective order in the applicable state actions. If that is not the case, please speak up now. No one spoke up, so please proceed. Thank you.

BY MR. CRUEGER:

Q. Good afternoon.

A. Good afternoon.

Q. So this is your fact deposition after your 30(b)(6) deposition. There's going to be a little bit of overlap by necessity, but we're trying to avoid that, and we will get

started.

What did you do to prepare for your fact deposition, anything different?

A. No.

Q. We asked you before, this is not the first time you've been deposed, obviously, correct?

A. Correct.

Q. I think you said you were deposed twice already?

A. Yes.

Q. Have you ever testified at trial?

A. No.

MR. CRUEGER: Given our system of the massive table, I'm just going to hand exhibits around like we were doing before.

(Document marked for identification as Exhibit Fanelli-1.)

BY MR. CRUEGER:

Q. So Exhibit 1 is just the Second Amended Notice of Deposition.

Have you ever seen this?

A. I don't believe so.

Q. Okay.

MR. SNAPP: Could you hand around a second copy when you hand them around, please.

MR. CRUEGER: Yeah, I just noticed that.

I'm going to hand you what's Exhibit 2, which is a copy of your CV.

(Document marked for identification as Exhibit Fanelli-2.)

BY MR. CRUEGER:

Q. Is this a true and accurate copy of your CV, Dr. Fanelli?

A. Yes.

Q. Let's just make a quick record of this. How long have you worked at Purdue?

A. Since December 2000.

Q. And are you an employee?

A. Yes.

Q. Are you an employee of Purdue Pharma, L.P.?

A. Yes.

Q. Are you an employee of any of the other entities?

A. That's my legal employer.

Q. Do you work for any of the other Purdue entities?

A. Depending on -- as the head of regulatory, there are other entities. For instance, we end licensed the product, and that was under Purdue Pharmaceutical Products, L.P. So that's an example.

Q. And just so that we speak in clear English, end licensing means what?

A. A product that another sponsor had the legal or the regulatory responsibility for that then became the regulatory and ownership of Purdue.

Q. A sponsor being -- is that another Purdue affiliated company?

A. No, no, that's an outside, outside of the Purdue group of companies.

Q. So is that just like licensing and patent?

A. Yes, or a product.

Q. Okay. Do you do any work for Rhodes Pharmaceuticals?

A. No.

Q. Could you tell me what Rhodes Pharmaceuticals is?

A. Rhodes Pharmaceuticals, there's -- yeah. Rhodes Pharmaceuticals is -- has generic products, you know, is my understanding. I don't know the full -- as I say, I'm not part of that company. We do interact.

Q. And what do you mean when you say you interact, what do you do?

A. An example is MS Contin, which Purdue got approved, was -- they sell a generic of that product, and they are currently, at least as of today, they are commercializing the product.

Q. "They" being Rhodes?

A. Rhodes Pharma -- or the firm you said, sorry.

Q. Rhodes Pharmaceutical?

A. Yeah.

Q. Or Rhodes Pharma?

A. Yeah.

Q. We can call it the same way. We don't have to say the long word all the time.

A. Yes.

Q. Do they also sell an immediate-release Oxycodone product?
A. I believe they do.
Q. And they sell generics, correct?
A. Yes.
Q. And are they owned by the same owners of Purdue?
MR. SNAPP: Object to the form.
THE WITNESS: Ownership, I'm not aware of the -- you know, the details of the ownership. I know that the Board of Directors -- you know, it's been split up. There are common individuals on the different boards, those boards.
BY MR. CRUEGER:
Q. The different boards being the boards of Rhodes Pharma and the boards of?
A. Purdue Pharma.
Q. Purdue Pharma?
A. Correct.
Q. Now, you have a Master's degree?
A. I have a Ph.D. I have a Master's degree as well.
Q. So, yes, you have a Master's

degree?

A. Yes, I do. Sorry.

Q. What is your Master's in?

A. It's in -- I'm trying to remember what we called it back then -- psychobiology or physiological psychology.

Q. Could you just explain very briefly what that is?

A. Sure. It was -- when I was at the State University of New York at Binghamton, part of that, the Ph.D. program had a interim Master's, where an area of research is defended in a Master's thesis that is written, and that's what that is.

Mine was looking at behavioral of different animals in learning models.

Q. And now we'll get to your Ph.D.

You have a Ph.D.?

A. Yes, I do.

Q. And what's your Ph.D. in?

A. It's in physiological psychology is the -- which I think I referred to earlier -- is similar to neuroscience today.

Q. And to explain that to someone

who is not a Ph.D. in those areas, what does that actually mean? Like, what is that a degree in?

A. So a Ph.D. is a -- requires a thesis and a years of research, well, it can be whatever it is with a novel test of a hypothesis, and it's a course of study and research to defend -- that is defended and a degree is granted.

Q. I was unclear. What is the field that you have a Ph.D. in? Can you explain that in less technical terms than the title?

A. Okay, sorry. I guess in terms of the scientific area?

Q. Yes.

A. I guess the area of study would be the functioning of certain brain regions in different learning and memory models.

Q. Now, you haven't always worked at Purdue Pharma, correct?

A. That's correct.

Q. So I'm on your CV. If you look on page 2 it says from July of 1985 to April of 1988, you worked at the NIDA Addiction Research

Center?

A. Yes.

Q. What did you do there?

A. Numbers of experiments across the time. I was a staff fellow, which reported in to laboratory that was investigating the role -- similar as in my Ph.D, but expanded neurochemical systems around the behavior and as it relates to addiction.

Q. Addiction to what?

A. On the project we were looking at, it was on over the course of three years multiple investigations that were of -- part of the -- and, by the way, NIDA stands for the National Institute on Drug Abuse, so that were a part of the course of that.

Q. Did any of your study involve opioids?

A. Yes.

Q. What type of opioids?

A. So I was looking at -- and there's -- there are publications. Again, I was in Edy London's lab, and we looked at metabolic glucose, it's similar to a PET imaging of the

brain in animals, looking at areas of the brain that were involved of substances of abuse, and we looked at different types of opiates, B1 agonists, delta agonists, and looked for the different areas of the brains that were involved.

Q. So you were studying the effect on the brain?

A. Yes.

Q. Very quickly, you worked at Bayer?

A. Correct.

Q. And then at Bayer you were doing -- I guess we would call you're doing science; you weren't always doing regulatory work?

A. Correct. For the first -- from I think -- well, it says on there. Started in '88 and moved into regulatory in '97, so almost a decade.

Q. And then from Bayer you came over to Purdue Pharma in December of 2000, correct?

A. Correct.

Q. Now, do you have a role in the

approval of reformulated OxyContin?

A. In the approval? You mean in terms of -- well --

Q. Well, let's just talk about reformulated OxyContin.

A. Yes.

Q. Can we agree that's supposedly the abuse deterrent --

A. Correct.

Q. -- version of OxyContin?

A. Correct.

Q. Okay. Just as a reminder, I have to finish and you have to start; otherwise, the court reporter gets angry.

A. I apologize.

Q. And now, the FDA approved reformulated OxyContin, correct?

A. Correct.

Q. Did you have any role in submitting those documents to the FDA?

A. For the NDA for the reformulated?

Q. Yes.

A. I was not the -- we talked about FDA liaisons. Do you want me to -- anyway, I

was not the FDA liaison on that submission.

Q. Who was?

A. It was either -- we could look at the submission letter. I believe it might have been Beth Conley.

Q. Do you have a role now as --

A. Yes.

Q. -- working with the ADF and reformulated OxyContin?

A. Yes.

Q. And what is that role?

A. I am now the FDA liaison on that product, so I would be the prime person communicating with FDA on that work.

Q. And when did you take on that role?

A. Beth Conley left Purdue -- it's within a year. So when she left the company, I took that over.

Q. Just to talk quickly, how are -- you said you were an employee of Purdue Pharma, correct?

A. Yes.

Q. How are you paid, a salary?

A. Yes.
Q. Do you receive a bonus?
A. Yes.
Q. How is your bonus calculated?
A. It's based on -- it's changed. You want today, 75% based on company performance and 25% on meeting my personal objectives. It's actually company performance against the corporate objectives.
Q. Just briefly explain what you mean by that. Is it tied to sales, or is it tied to some pre -- your -- that part of your bonus, or is it tied to some predetermined metric?
A. It's not tied to sales. It's tied to -- so I'm an R&D -- my personal is beginning of the year we have objectives for myself as the head of regulatory, and it's dependent on -- the 25% is how well we do against those objectives, and then the corporation has objectives at the beginning of the year and how well the corporation does against those objectives.
Q. And by "well," that's due --

that's measured in revenue?

MR. SNAPP: Object to the form.

THE WITNESS: I don't -- that could be one of the objectives on there, but I think it may be one of the objectives.

BY MR. CRUEGER:

Q. Can you tell me what the objectives are?

A. No, I can't.

(Document marked for identification as Exhibit Fanelli-3.)

BY MR. CRUEGER:

Q. I've just passed over what is Exhibit 3.

By the way, just on Exhibit 2, I don't know if you know, your Social Security number is on there. You might want to --

A. It's not on -- yeah.

Q. You might want to delete that off so...

A. Thank you.

Q. Exhibit 3 I just want to ask you if this looks like a true and accurate report of

your salary from 2000 to obviously June of 2018?

A. It appears to be.

Q. Okay.

A. Sorry, can I --

Q. Sure.

A. (Witness reviews document.)

Q. Are you looking at Exhibit 3?

A. Yes. Sorry.

Q. Okay.

A. Oh, okay. So 2018 must be part year.

Q. Yes, yes, it goes through June of 2018.

A. Got it, thank you. Then it's accurate.

Q. Mr. Fanelli, we're going to talk a little bit about really kind of three general areas, a little bit about your role in the company and what you're doing, talk a little bit about the ADF and what that is, the abuse deterrent formula.

Is it a formula or formulation?

A. Formulation.

Q. And then we're just going to talk

about the process of basically the history of where that -- where the abuse deterrent formulation started and then where is it going, okay?

A. Yes.

Q. So those would be the three general things.

So let's just, you know, lay a little background to some of this is Purdue sells OxyContin, correct?

A. Say it again.

Q. Purdue sells OxyContin?

A. Yes.

Q. And OxyContin, the primary active drug is -- ingredient is Oxycodone?

A. Yes.

Q. And that's an opioid, correct?

A. Correct.

Q. And it's a dangerous drug, correct?

A. It's a new opiate agonist that's a Schedule II, which is the highest level of approved agents that -- in that class for abuse and diversion, yeah, with risks of abuse and

diversion.

Q. So it's dangerous, correct?

A. Yes.

Q. And it can kill you?

MR. SNAPP: Object to the form.

THE WITNESS: Yes, if -- yeah, go ahead.

BY MR. CRUEGER:

Q. And it can kill you by overdosing, correct?

A. There have been overdoses with Oxycodone, yes.

Q. But that's -- you take too much of it and you overdose and then you die, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MR. CRUEGER:

Q. So and exactly how does it kill someone?

A. I'm not a physician. What's reported in the package insert are risks related to the product. The primary risk is respiratory depression, and that's the prime risk around an

overdose with new agonists.

Q. So what is respiratory depression?

A. It's depression of the breathing, so there would be a slowing of the breathing rate.

Q. It slows down your breathing, and eventually your lungs fill up with liquid, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not aware of the full -- it's not part of my background.

BY MR. CRUEGER:

Q. So you know it can kill you, but you don't know exactly how?

MR. SNAPP: Object to the form.

THE WITNESS: I don't know. You asked about filling up the lungs. As I say, the primary risk is around respiratory depression.

BY MR. CRUEGER:

Q. What I'm just -- what I'm trying to do is get rid of the sanitation we tend to

put around these things. We try to clean up the whole process, and respiratory depression is a very nice word to describe you stop breathing and you die, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It is talking about the respiratory rate, if it falls too low, it can result in death, yes.

BY MR. CRUEGER:

Q. And so when we talk about people overdosing, that's the actual thing that happens to them, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That's one of the things, yes.

BY MR. CRUEGER:

Q. And it's also -- OxyContin is also dangerous because -- or opioids in general are also dangerous because there's a risk of addiction, correct?

A. Yes, there is a risk of addiction, it's part of the warnings, right, listed in the black box warning as well.

MR. CRUEGER: So I'm going to

hand you what's been labeled Exhibit 4.

(Document marked for identification as Exhibit Fanelli-4.)

BY MR. CRUEGER:

Q. Now, you're aware there's been a rise in prescription overdose deaths over the past ten years, correct?

A. Yes.

Q. Have you seen this graph before?

A. It looks familiar. I don't know if it's the exact one, but I've seen versions of this in the data.

Q. And the purple line "Commonly Prescribed Opioids," that would include OxyContin, correct?

A. Correct.

Q. And it's grown pretty high since 1999, correct?

MR. SNAPP: Object to the form.

THE WITNESS: According to this presentation, it has grown over this time period.

BY MR. CRUEGER:

Q. And in 1999 it was just a little

over one death per 100,000 people, correct, just commonly prescribed opioids, not all of them, so the purple line?

A. That's what's on this graph. That's what it notes.

Q. And by 2007 it looks like it's a little bit over four people, four deaths per 100,000 people, correct?

A. Yes.

Q. And then by 2011 it seems to be getting up to about almost five deaths per 100,000 people, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That's what this figure is showing, yes.

BY MR. CRUEGER:

Q. And by 2015 it's still up, it looks like it's even a little higher than five deaths per 100,000 people, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It looks to me like it's a little lower but --

BY MR. CRUEGER:

Q. It's a little tough to tell

without the graphing, but it's --

A. Yes, and without the data.

Q. So -- and it's been growing as the number of prescriptions in the United States has been growing too, correct?

MR. SNAPP: Object to the form.

THE WITNESS: This graph is deaths per 100,000 prescriptions.

BY MR. CRUEGER:

Q. 100,000 people?

A. Oh, population, right.

Q. So what I'm asking, do you know whether the amount of -- the number of prescriptions for opioids has increased from 1999 to 2016?

A. It has increased since 1999.

Q. And so has the number of deaths?

MR. SNAPP: Object to the form.

THE WITNESS: That's correct.

BY MR. CRUEGER:

Q. Do you think, Mr. Fanelli, that there's a correlation between the increase in the number of prescriptions and the increase in overdose deaths from prescription opioids?

MR. SNAPP: Object to the form.

THE WITNESS: There is -- there is an increase or at least the prescription opioids are -- as of today, there's a significant decrease since the time the graph you show here, but there has been a increase in both of them, but correlation does not indicate causation, but there has been a correlation in the two.

MR. CRUEGER: I'll hand you Exhibit 5.

(Document marked for identification as Exhibit Fanelli-5.)

BY MR. CRUEGER:

Q. Do you know, Mr. Fanelli -- Dr. Fanelli, between with the increase in prescriptions for opioids and the increase of number of deaths, has there been any decrease in reported pain in the United States?

A. I'm not aware of the numbers of reporting pain.

Q. So do you ever go on the CDC website?

A. I have.

Q. And do you ever go on the CDC website and just see the information about the prescription opioids?

A. In the past I have done that.

Q. So this is a copy of -- Exhibit 5 is a copy from the frequently asked question section of the CDC website.

Have you looked through the frequently asked questions before?

A. No, I have not.

Q. So, according to here, it says, the second sentence in the "Why is the guideline needed in the United States?"

Do you see that section?

A. Yes.

Q. So it says, "The amount of opioids prescribed and sold in the United States quadrupled since 1999, yet there has not been an overall change in the amount of pain that Americans report."

Have I read that correctly?

A. Yes.

Q. Do you have any information to

dispute that?

A. No, I don't have any different information.

Q. Do you know if Purdue has any information to dispute that?

A. I'm not aware of whether or not Purdue has that information.

Q. So who is Dr. Haddox or Haddox, H-a-d-d --

A. Haddox is correct. Dr. David Haddox is, was, I believe he still is head of our health policy I think was the name of the department. He was on the org charts we talked about yesterday.

Q. What's his role at Purdue?

A. I know that he was head of that department.

Q. But what does that department do?

A. Health policy -- should I pass this?

Q. Just set that aside for a second.

A. Yeah, okay, sorry.

Q. It's just the process of getting it around the large table to you.

A. Understand. So your question again?

Q. I mean, you said Dr. Haddox is in health policy.

What does he do, though, at Purdue?

A. So health policy group, it's moved around in terms of it was a part of medical affairs or an independent department, so it's changed over time, but they work on and address policy issues in the corporation around healthcare.

Q. Can you give me an example?

A. So, for instance, if there are -- you know what, my interactions with Dr. Haddox in that group are mostly around submissions to FDA of -- if there was something they came up with that was going to be submitted to the agency. So most of my interactions with Dr. Haddox were in group discussions of those. Whether or not, for instance, there were guidelines around treatment of pain that were being discussed and if we were -- there's one example, if Purdue was going to provide some

input into that public discussion.

(Document marked for identification as Exhibit Fanelli-6.)

BY MR. CRUEGER:

Q. So if you look at what's been labeled Exhibit 6 that was just passed to you.

A. Yes.

Q. This is an e-mail from Dr. Haddox to you, correct?

A. Yes.

Q. And it's sent in September -- on September 17th, 2004, correct?

A. Yes.

Q. And at this time I believe, according to your resume, you were the senior director of regulatory affairs?

A. Correct.

Q. So what was your job as a senior director of regulatory affairs during this time? You can take time to read the e-mail if you want to.

A. Yeah, could I do that? (Witness reviews document.) So I'm trying to remember -- you asked -- can you ask the question again.

Q. I was asking what were your job responsibilities as a senior director in this time frame, 2004?

A. So I'm trying to remember if I was the head of the group, but I think that happened in 2006. So I would have been an individual FDA liaison but one of the senior ones at that time.

Q. And he's sending you the subject is language, so why is Dr. Haddox sending you this, this e-mail?

A. I don't recall why Dr. Haddox sent it. It has a D, it looks like it's -- well, I'm speculating. It's taken from something else.

Q. And he's talking about -- well, I'll let -- be curious in your understanding, what is Dr. Haddox talking about in this e-mail?

MR. SNAPP: Object to the form.

THE WITNESS: Again, it's, you know, seeing that number D in front of it, it looks like he's taken this from somewhere else and sent it to me, but I -- and it just says language, so I'm

not sure. You know, I don't recall back, you know, that long ago why he would have sent that to me.

BY MR. CRUEGER:

Q. And what is this information that he's sending you?

A. He talks about data from the NASDUH, it's sometimes referred to, or SAMHSA, National Survey on Drug Use and Health.

Q. And what is the data about?

A. It's talking about nonmedical use of prescription analgesics.

Q. And the last sentence, can you read that, please.

A. "This fact can be used to interpret the following data to make valid inferences about the rate of iatrogenic addiction."

Q. And can you just briefly explain what is iatrogenic addiction?

A. It's a term that has been used for addiction for increases in -- for instance, increases in opiate requirements around pain when -- with taking the medication is my

understanding.

Q. Is it addiction that occurs when a patient takes medicine, an opioid pursuant to a prescription?

MR. SNAPP: Object to the form.

THE WITNESS: So as we talked about, my experience and work at the Addiction Research Center is on the basic physiologic mechanisms.

This is a clinical definition, but my understanding, I'm not the expert in that area, but I don't have -- I don't disagree with your conclusion.

BY MR. CRUEGER:

Q. And they have some numbers in here, one is for 2002 that 8.5% met the DSM-IV criteria for dependence to pain relievers and that number in 2003 was 8.7%, 8.07%, correct?

A. That's what it says here, yes.

Q. Are those numbers high?

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. In your opinion?

A. I think we've talked about the --

I have no scientific basis to know -- to qualify that as such.

Q. So what does that mean when you say you have no scientific basis, that you just don't know if that number is high or if it's low?

MR. SNAPP: Object to the form.

THE WITNESS: How to rate those numbers based on other factors in the environment or in the -- yeah, just leave it at that.

BY MR. CRUEGER:

Q. And as of 2004, am I correct that Purdue had no study about the risk of addiction among patients treated with extended-release opioids?

MR. SNAPP: Object to the form.

THE WITNESS: What do you mean by "study"?

BY MR. CRUEGER:

Q. Had Purdue done any study, a controlled study, any type of study to get an idea about the risk of addiction among patients who were treated with extended-release opioids

for chronic pain?

MR. SNAPP: Object to the form.

THE WITNESS: No.

BY MR. CRUEGER:

Q. And you mentioned that you had talked to Dr. Haddox about guidelines?

A. (Witness shakes head.)

Q. Is that yes or no? You just have to...

A. Yes. I don't remember the details. For instance, the CDC guideline, I think we referred to it, I know I had a conversation about that, but, again, it wouldn't have been part of my function as the head of regulatory to -- it would be more of, you know, how do we interact with FDA about those, and that would have been the role.

Q. So Dr. Haddox, was he trying to get the -- would he be talking to you about the guidelines because he wanted the FDA to do something about the guidelines?

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. I'm trying to understand why

would he be talking to you about the guidelines?

A. Guidelines from government agency or physician groups or whatever would be reviewed, and it probably wasn't a one-on-one. It might have been in a discussion, does it have any impact on our submissions.

Q. And these are guidelines for the treatment using opioids to treat chronic pain?

A. It could be.

Q. Now, I only have one copy of this, but we've talked a little about -- it's been mentioned a few times that Purdue pled guilty, correct?

A. We have talked about that, yes.

Q. And they pled guilty to making false and misleading statements about the risk of addiction, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

MR. CRUEGER: I'm going to hand you what's been labeled Exhibit 10.

(Document marked for identification as Exhibit Fanelli-10.)

BY MR. CRUEGER:

Q. Dr. Fanelli, so let's just do a few background things before we move on to that.

So you know that Purdue pled guilty, correct?

A. Yes.

Q. And it was 2007, correct? I'll represent to you it was 2007.

A. Yes.

Q. And you were working at Purdue at the time, correct?

A. Yes.

Q. And you had a fairly high up position in the company at the time, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I was we say a senior director at the time.

BY MR. CRUEGER:

Q. Did you ever read the indictment, the Information?

A. No.

Q. Did you ever read the Agreed Statement of Facts?

A. No.

Q. Why not?

A. That was the responsibility of others. I learned from them what was Purdue's -- Purdue's response as it relates to the interaction with the agency, the FDA.

Q. But aside from your responsibilities as an employee, it's not every day that your employer pleads guilty to a federal crime, is it?

MR. SNAPP: Object to the form.

THE WITNESS: Can you repeat the question. Sorry.

BY MR. CRUEGER:

Q. It's pretty unusual for your employer to plead guilty to a federal crime, correct?

A. Yes.

Q. And so my natural inclination would be to figure out what my employer did that was considered to be a federal crime, so I'm wondering, did you do anything to figure out what Purdue did that it pled guilty to a federal crime?

MR. SNAPP: Object to the form.

THE WITNESS: I relied on my

colleagues who examined that, specifically members of the law department, but others, to be informed on it.

BY MR. CRUEGER:

Q. And how did you learn of the -- of the information and guilty plea?

A. I thought that -- that's what I just said, from my colleagues who had the responsibility to review that.

Q. But I'm asking, so was there an e-mail that went around, or did some person come and tell you, or did they have a meeting of all the employees, or how did that message go around the company?

A. You know, I don't remember the exact details.

Q. And you said your colleagues, so who were you talking to, like who talked to you about the -- to explain the guilty plea to you?

A. It would have been members of the law department.

Q. So really today is kind of like the first day that you've -- today and yesterday

are really the first days that you've looked at the Agreed Statement of Facts and the Information and the guilty plea?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MR. CRUEGER:

Q. Did you look at them -- you didn't look at them to prepare for your -- either the 30(b)(6) or your fact deposition?

A. I can't remember -- I can't remember if I did or not.

Q. So you've never looked through the Agreed Statement of Facts and figured out exactly what Purdue did to violate the law?

MR. SNAPP: Object to the form.

THE WITNESS: Correct. I relied on my colleagues to provide that information.

BY MR. CRUEGER:

Q. If you can go to page 5 of that exhibit, the agreed statement of facts, so it's paragraph 20. And it says, "Beginning on or about December 12th, 1995, and continuing until on or about June 30th, 2001, certain Purdue

supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows."

And I would just like you to read out loud paragraph 20b.

MR. SNAPP: Object to the form.

THE WITNESS: Told Purdue sales representatives they could tell healthcare providers that OxyContin potentially causes less chance of addiction than immediate-release opioids.

BY MR. CRUEGER:

Q. So did you know that Purdue had done this?

MR. SNAPP: Object to the form.

THE WITNESS: Yes, I was aware of that.

BY MR. CRUEGER:

Q. And that statement that you just read, when they tell sales -- when sales

representatives would tell healthcare providers that OxyContin potentially creates less chance for addiction than immediate-release opioids, that is a false statement, correct?

MR. SNAPP: Object to the form.

THE WITNESS: So a statement that was in the original package insert about the long-acting nature compared to -- it doesn't say compared to immediate-release, but the long-acting had a less chance of addiction was in the original package insert, but is no longer in there, based on the lack of scientific evidence.

BY MR. CRUEGER:

Q. Well, first of all, I believe the package insert, it was a little bit less definitive in that, correct, it was believed, correct?

A. That's correct.

Q. And it didn't actually say who believed it, correct?

A. It was part of the approved label.

Q. But it didn't say who believed it, correct?

A. It did not ascribe it.

Q. And just because it's in the package insert, that doesn't necessarily make it true, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It's approved based on the scientific evidence as approved by FDA.

BY MR. CRUEGER:

Q. But just because it's approved, if it's incorrect, it's incorrect?

MR. SNAPP: Object to the form.

THE WITNESS: If something is incorrect, it is incorrect.

BY MR. CRUEGER:

Q. And how you answer that actually raises a question.

So if the label says -- an FDA approved label says that extended-release opioids are believed to reduce the risk of addiction, but the company knows that's untrue, should the company still tell the public that

extended-release opioids may reduce the risk of addiction?

MR. SNAPP: Object to the form.

THE WITNESS: Purdue has, as recently as within the six months, worked with FDA to revise labeling based on new data that's available. I'll just stop there.

BY MR. CRUEGER:

Q. But that's not my question.

My question is because you seem to say that if the FDA label says -- has a statement, in this case, that it's believed that extended-release opioids may reduce the risk of addiction, that Purdue can market that, using that statement, even if it knows it's untrue and inaccurate?

MR. SNAPP: Is there a question? Objection to form.

BY MR. CRUEGER:

Q. Is that your belief?

MR. SNAPP: Object to the form.

THE WITNESS: No.

BY MR. CRUEGER:

Q. Okay. So if the company knows the statement is untrue, even if it's in the label, would you agree with me that the company should not market that statement that it knows it's untrue using -- should not -- let me strike that.

If the company knows that the statement in the label is untrue, then you would agree with me that the company should not use that statement to market the opioids to the public, correct?

MR. SNAPP: Object to the form.

THE WITNESS: So this is -- statements -- we talked about that earlier, statements in the label are based on available evidence.

The statements that end up there are a scientific evaluation by both the sponsors and FDA. FDA has reasons for putting things in a label that the company may not have, but it's all based on the level of science at the time.

BY MR. CRUEGER:

Q. But I'm asking you a slightly

different question, and I'm not even asking you a legal liability question. That's a different question.

I'm just asking you that if the company knows that extended-release opioids do not reduce the risk of addiction, should it market that feature to the public just because it's in the label?

MR. SNAPP: Object to the form.

THE WITNESS: There would be a reason something is in the label, and it's more complicated than that hypothetical that you proposed.

BY MR. CRUEGER:

Q. Guidelines I don't think it's -- what makes it more complicated if it's -- if the company knows it's an untrue statement?

MR. SNAPP: Wait for the question to come.

BY MR. CRUEGER:

Q. What makes it complicated if the company knows the statement in the label is untrue or inaccurate, what makes it complicated as to whether or not the company should use that

statement to market the opioids to the public?

MR. SNAPP: Object to the form.

THE WITNESS: In that hypothetical if it was untrue the company should not promote it.

BY MR. CRUEGER:

Q. And by the way, nothing -- nothing stops the company from withdrawing its own drug from the market, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That's correct.

BY MR. CRUEGER:

Q. Okay. And nothing stops the company from determining that its drug is unsafe, correct?

MR. SNAPP: Object to the form.

THE WITNESS: The company is required to continue to evaluate and we talked about it, periodic reports at least once a year if not more on the benefit-risk of a product.

BY MR. CRUEGER:

Q. Now, we talked about the statement that's in the agreed statement of

facts in paragraph 20B and you made a reference that originally in the label there was a statement that it was believed that the extended-release opioid may reduce the risk of addiction, correct?

A. Yes.

Q. When did that come out of the label?

A. I don't remember the exact date.

Q. Was it off -- did that come out of the label by 2000, by the time you started at Purdue?

MR. SNAPP: Object to the form.

THE WITNESS: I don't remember. Again.

BY MR. CRUEGER:

Q. It would have been out of the label by 2007, when this plea agreement took place, correct?

A. Correct.

Q. So in 2007 if a person told a healthcare provider so if a Purdue representative told a healthcare provider that OxyContin creates less chance for addiction than

immediate release opioids that would be either a false or misleading statement, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Can you repeat the question.

BY MR. CRUEGER:

Q. If in 2007 a representative told a healthcare provider that OxyContin potentially creates less chance for addiction than immediate release opioids, that would be a false or misleading statement, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Determining how -- the exact -- this is how reviews and everything, it really depends on any statement how it said what actual the statement is and the context it occurred.

BY MR. CRUEGER:

Q. So let's just look at paragraph 20B in that statement.

A. Which one?

Q. Paragraph 20B, page six I believe it is, the one that you read aloud.

So that exact statement in paragraph 20B, that would be false and misleading, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Again, it would depend on how it was stated.

BY MR. CRUEGER:

Q. If it was stated just like that in 20B --

A. That second part of the sentence?

Q. Well, 20B is one sentence -- yeah, that OxyContin potentially creates less chance for addiction than immediate release opioids?

A. That's correct.

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. That's correct, that it would be false and misleading?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

MR. CRUEGER: So I'm going to hand you what's been labeled as Exhibit 7.

(Document marked for identification as Exhibit Fanelli-7.)

BY MR. CRUEGER:

Q. If you could just take time to read through the e-mail, Dr. Fanelli.

A. (Witness reviews document.)

Q. Just tell me when you're done.

A. I've read it, looked through it.

Q. Would you agree that this is a true and accurate copy of the e-mail?

A. Yes.

Q. So if you look at the second page that ends in the Bates number three confusingly?

A. I see.

Q. So starting with the e-mail that's from you sent on -- sent in 2012 to Lisa Basham, she works at the FDA, correct?

A. Yes, I believe she still does. It's Lisa Basham, who is a regulatory project -- was a regulatory project manager in the Division of Anesthesia, Analgesia and Addiction Products. She may no longer -- she may have moved, but I believe she's still at FDA.

Q. And the subject is about

OxyContin labeling?

A. Correct.

Q. And were you trying to get a change in the label?

A. This is discussing a change to the OxyContin label, but I don't -- I'm not sure where it initiated from. As we talked before suggestions for changes may come from the sponsor, could come from FDA. If you look at the first e-mail, the first e-mail came from Lisa Basham and says, we're all working on this, we suggest the following, so I don't actually recall who initiated the conversation.

Q. And you're sending her a -- I guess some proposed language for the label?

A. So -- yes.

Q. And because there's no color, it's a little difficult to tell, but it looks like the proposed -- of the language that you're proposing is in the shaded area?

A. Yeah, the first e-mail is FDA says they're suggesting this, then we -- I guess -- I have to --

Q. But just quickly so the --

A. The highlighted, it looks like that's the grayish is what we proposed suggested back.

Q. So there's the -- just to read the sentence, it says, "published relative potency data are available" and then the -- you would agree with me that then the proposal that Purdue is asking for is "and may be referred to in Clinical Practice Guidelines such as those published by the Veterans Health Administration Department of Defense and American Pain Society," correct?

A. Yes.

Q. And then the FDA, her response is on the first page, and her response is -- well, actually, she has an e-mail it says "Sharon's response." Who is Sharon?

A. That's Dr. Sharon Hertz, who's the -- I don't recall if she was -- but currently she is the division director at the Division of Anesthesia, Analgesia, and Addiction Products, Dr. Sharon Hertz. I'm not aware, we looked at letters yesterday, Bob Rappaport was -- could have been the head at the time,

but, anyway, this is either a medical officer or she might have been a deputy director at the time.

Q. So the short answer, she works at the FDA?

A. Correct.

Q. So and this is her comment is, "As I mentioned when we spoke, we don't like to refer to specific guidelines in labeling because they can change and then the labeling reference may no longer be appropriate. Therefore I removed the reference to the VA and APS," correct?

A. That's what it says, yes.

Q. So they removed the reference to the Veterans Health Administration, Department of Defense guidelines and also the American Pain Society guidelines, correct?

A. Correct.

Q. And then you forwarded the e-mail to -- it must have been to Bridget Martell?

MR. SNAPP: Object to the form.

THE WITNESS: It doesn't -- well, somehow she got this. It doesn't show

my forwarding.

BY MR. CRUEGER:

Q. Correct, but somehow it gets to her, correct?

A. Correct.

Q. Who is that? Who is Bridget Martell?

A. She's no longer at the company. Obviously, she was there at this time. She was -- I don't remember her title. She was in a medical affairs department.

Q. And she says "sad the strategy and rationale did not work," correct? So they wanted the -- well, the next sentence is "It seems we are left convincing legal that the general reference allows us to detail appropriate association guidelines," correct? That's what it says?

A. That's what it says, yes.

Q. So Purdue was looking to change the label so that it could detail doctors using those two guidelines, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I don't recall this

specifically, but that appears to be what that says. She's not in our sales organization, so I'm not -- I don't know how she's describing detail.

BY MR. CRUEGER:

Q. But, clearly, someone at Purdue wanted to use the American Pain Society guidelines to sell OxyContin, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I would not know if it's relate -- with that intention.

BY MR. CRUEGER:

Q. But you were proposing the change to the FDA, correct?

A. Correct.

Q. By "you" I mean you, not Purdue, you, Dr. Fanelli, were sending the change to the FDA, correct?

A. I was involved in the e-mail correspondence back and forth with Lisa Basham, who was a project manager with Dr. Hertz.

Q. And who at Purdue, did you -- was it your idea to include the reference to the American Pain Society guidelines?

MR. SNAPP: Object to the form.
THE WITNESS: Not mine individually. I mean, it would have been -- come from the medical affairs department.
BY MR. CRUEGER:
Q. Do you recall who?
A. No, I do not.
Q. Did you talk to Dr. Haddox about this change?
A. I could not remember whether I did or not. It doesn't -- he's not on the list.
Q. Do you know -- did you read the guidelines, the American Pain Society guidelines?
A. Not in detail.
Q. But you did read them?
MR. SNAPP: Object to the form.
THE WITNESS: I don't recall reading those guidelines, no.
BY MR. CRUEGER:
Q. Do you know who the American Pain Society is, Dr. Fanelli?
A. No, not in detail. I mean, I've

heard of them in correspondence such as this, but the actual makeup would just be a -- from my hearing about it, not an investigation of it.

Q. Do you know whether Purdue provides any support to the American Pain Society?

A. I do not know.

Q. Just to clean this up quickly, so I just want to be clear on this, so Purdue wanted to change the label for a reason that's really due to marketing, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I would not agree to that.

BY MR. CRUEGER:

Q. How would you -- if they want to use the American Pain Society guidelines to detail doctors, that would be marketing, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Can you repeat the question.

BY MR. CRUEGER:

Q. If they wanted to use the

American Pain Society guidelines to detail doctors, that is marketing, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It could be referred to as that, yes.

BY MR. CRUEGER:

Q. And if you change the label in the way that Purdue was proposing to change the label, that would be marketing consistent with the FDA label, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Yes. So could you repeat it. Sorry. I want to make sure I got the right --

BY MR. CRUEGER:

Q. If the FDA approved the label change that Purdue was proposing, then Purdue could market or detail doctors using the American Pain Society guidelines and claim that they were marketing consistent with the label for OxyContin, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That is correct.

MR. SNAPP: Before we move on to

another exhibit, can we take a five-minute break. We've been going 66 minutes.

MR. CRUEGER: Let's just stop this and then we're at a stopping point.

THE WITNESS: Finish this one?

MR. SNAPP: Are you done with that one?

MR. CRUEGER: We're done with that one.

MR. SNAPP: So can we take a break?

MR. CRUEGER: Sure, if you want to take a quick break.

THE VIDEOGRAPHER: Stand by. Remove your microphones. The time is 2:09 p.m., off the record.

(Brief recess.)

THE VIDEOGRAPHER: Okay. We are back on the record. The time is 2:23 p.m.

MR. CRUEGER: I'm going to hand you what I've labeled Exhibit 8, Dr. Fanelli.

(Document marked for identification as Exhibit Fanelli-8.)

BY MR. CRUEGER:

Q. Have you seen this document before?

A. I don't recall reviewing this document in this state.

Q. What was the last part that you said?

A. As such, exactly like this.

Q. But you've heard of this document before?

A. Yes.

Q. Okay. Again, you have to remember that I have to be able to finish before you can start talking.

A. I apologize.

Q. It's not a natural way of doing conversation, so don't worry about it.

If you go to page 4 of the report.

A. The page numbers on top?

Q. The page numbers on the top, correct. There's a "Figure 1: Manufacturer

Payments to Selected Groups, 2012-2017," and there's an entry for Purdue.

Do you see where I am in the first column -- the second column?

A. Yes.

Q. And if you go down, there's the American Pain Society?

A. Yes.

Q. And you see there's a little over $542,000 paid to the American Pain Society?

A. I see that.

Q. Were you aware of Purdue's contributions to the American Pain Society?

A. No.

Q. Were you aware of any of these other companies' contributions to the American Pain Society?

A. No.

Q. When you submitted the proposed label change that referenced the American Pain Society, did -- are you aware of anyone at Purdue telling the FDA about the payments to that society?

MR. SNAPP: Object to the form.

THE WITNESS: No, I'm not aware.

MR. CRUEGER: So handing you what's labeled Exhibit 9.

(Document marked for identification as Exhibit Fanelli-9.)

BY MR. CRUEGER:

Q. These are the American Pain Society guidelines, correct?

A. I believe it's discussing that. I haven't seen it in this form that I recall.

Q. Well, you said you had read through the guidelines, correct?

A. I had -- I didn't -- I don't think I said I read through them. I had seen discussion of them, not from start to -- you know what I mean, I think I said that.

Q. I actually don't know what that means. Can you explain what that means?

A. So either -- I have seen them, yes. I have seen them, I'll say that.

Q. So is the distinction we're drawing here you've seen them, but you have not read them?

A. Correct. I had not done a

detailed reading through of the documents.

Q. But these are the guidelines that Purdue wanted to be referred to in the label so it could use them to detail doctors, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I'd have to look back to -- I don't -- I'm not aware of the timing of this or if it's the full and complete listing of it in this form.

BY MR. CRUEGER:

Q. And if you turn to page -- well, the page numbers up in the right-hand corner, it's page 117, 117.

A. Yes.

Q. In the second column, if you go all the way down to the bottom, it's the last sentence before the next section take starts as methadone.

Do you see where I am?

A. On top of the --

Q. On top of it.

A. Yeah.

Q. Starts with "proposed"?

A. I see that.

Q. So it says, proposed benefits of transitioning to long-acting opioids with around-the-clock dosing include more consistent control of pain, improved adherence and lower risk of addiction or abuse through well-conducted studies -- though well-conducted studies have not examined these benefits.

That's what it says, correct?

A. Yes.

Q. And these are the guidelines that Purdue wanted to use to detail customers?

MR. SNAPP: Object to the form.

THE WITNESS: Again, I'm not sure if this presentation is the exact version that FDA -- we were referring to at that time.

BY MR. CRUEGER:

Q. And this statement in this American Pain Society guideline, now we would agree that that is incorrect, that the use of long-acting opioids has a lower risk of addiction or abuse?

MR. SNAPP: Object to the form.

THE WITNESS: It says

well-conducted studies have not been conducted or well-conducted studies have not examined these.

BY MR. CRUEGER:

Q. Do you know of any evidence to support that statement?

A. Could you repeat -- the one on front.

Q. This last sentence, the proposed benefits of transitioning to long-acting opioids with around-the-clock dosing include more consistent control of pain, improved adherence and lower risk of addiction or abuse.

MR. SNAPP: Do you want to finish the sentence.

BY MR. CRUEGER:

Q. Though well-conducted studies have not examined the benefits.

Do you know of any -- any scientific evidence that supports the part of that statement that says it lowers the risk of addiction or abuse?

MR. SNAPP: Object to the form.

THE WITNESS: Those studies are

being conducted as we speak.

BY MR. CRUEGER:

Q. Did you know of any studies in 2012?

A. I'm not aware of studies at that time.

Q. In 2012 was the time when you were proposing to change the label with the FDA, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That we talked about --

BY MR. CRUEGER:

Q. In Exhibit 7, correct?

A. Yes.

Q. Dr. Fanelli, do you have any idea what the risk to the patient is if a doctor believes that the risk of addiction is lower if you're using extended-release opioids?

MR. SNAPP: Object to the form.

THE WITNESS: I think we talked about that the risk is still under discussion and scientific evaluation.

BY MR. CRUEGER:

Q. So you just -- it could be very dangerous, it could be dangerous, it could be --

A. Could you repeat the question. What could be dangerous?

Q. If a doctor believes that using extended-release opioids to treat chronic pain, there's a -- let me strike that.

If a doctor believes that there's less risk of addiction and abuse if he prescribes extended-release opioids to a patient to treat chronic pain?

MR. SNAPP: Object to the form.

THE WITNESS: I have -- I don't have any way to evaluate that.

BY MR. CRUEGER:

Q. So if you have no way to evaluate that, why was Purdue asking the FDA to change the label to include those guidelines?

MR. SNAPP: Object to the form.

THE WITNESS: We were responding to an FDA -- again, we don't -- I don't have the whole history or remember that every detail, but we were responding to an FDA request, and I actually don't

know the full rationale for including those at that time.

BY MR. CRUEGER:

Q. Certainly, you're not suggesting that the FDA was proposing that you include the reference to the American Pain Society guidelines in the label?

A. No.

Q. It's Purdue that was proposing it, correct?

A. Correct.

Q. And I believe you testified you don't know who at Purdue proposed it?

MR. SNAPP: Object to the form.

THE WITNESS: I don't know, yes, where it came from.

BY MR. CRUEGER:

Q. If I wanted to answer that question or if you wanted to answer that question, how would you go about figuring it out?

MR. SNAPP: Object to the form.

THE WITNESS: I would -- this part of that, those guidelines are -- I

would talk to folks in the medical affairs department.

BY MR. CRUEGER:

Q. Such as whom, who in particular?

A. Probably the head of that group, although Marcelo Bigal started recently, so I'd probably talk to Monica Kwarcinski.

Q. And does Purdue keep a record of when it's proposing changes to labels of how Purdue decided to propose lang -- let me strike that.

Does Purdue keep a record of how it came about to decide to propose certain language in a label?

A. We keep record of the -- depending on -- of course, it depends on exactly what it is. An example would be references if when we submit a label for review, there are annotations that reference where the evidence is from and so forth, but it really depends on the particular change.

BY MR. CRUEGER:

Q. I was thinking more along the lines is there a record of any -- a centralized

record of any discussion or the decision-making process within Purdue of we want to include this language in the label?

A. There is a record of all correspondence with FDA, but within it would depend on what that discussion is.

(Document marked for identification as Exhibit Fanelli-11.)

BY MR. CRUEGER:

Q. I'll hand you what's been marked Exhibit 11.

If you can take time to just read the e-mail and then tell me when you're done.

A. (Witness reviews document.)

I've read it.

Q. This is an e-mail, 2015, and it's referring to the LA Times. It's called LA Times Fact Pattern, but it's referring to articles that were in the LA Times.

Do you recall those articles?

A. I recall that there were articles, yes.

Q. Did you read any of them?

A. Yes.

Q. And can you just summarize for me so we don't have to go through the entire thing, what they're asking -- well, let's just make this clear, Robert Josephson, is that a -- that's a Purdue employee, correct?

A. Yeah, Bob Josephson is in our corporate communications group.

Q. And the other people, the other two people on here, these are also Purdue employees, correct?

A. Correct.

Q. And then it's CCing you. Did you do any work in formulating Purdue's response to the articles?

A. No.

Q. So you were just CC'd on the e-mail?

A. Correct.

Q. So you can just put that to one side.

So I just want to talk to you a little bit about the abuse deterrent formulation.

A. Sure.

Q. First, I just want to -- we talked about it very briefly before, but you said you were not the -- I can't remember the exact term, is it the chief liaison with the FDA --

A. Right.

Q. -- for the initial approval of reformulated OxyContin?

A. Correct.

Q. And that -- so what role did you play, if any, in between Purdue submitting the NDA for reformulated OxyContin and then it received approval in 2010, correct?

A. So I would have provided supervisory oversight to the prime regulatory folks at that time.

Q. Okay. And so what does -- I just want to get an idea of what that actually means.

Does that mean you review and approve everything before it's filed?

A. Not everything, but I would look at important items, give advice.

Q. Okay. So I want to just quickly talk about what abuse -- this means for

OxyContin, what abuse deterrent formulation means.

It's really about -- is it about tamper resistance, correct?

A. Yes.

Q. So it's making the pill harder to crush, correct?

A. That's one part, yes.

Q. And another part is then it makes it if you crush it, it's harder to either inhale or melt and put it up in a syringe, correct?

A. Correct.

Q. Is there anything else that it does?

A. You said inhale, yes, that's the -- that was the goals of the reformulation.

Q. So it's addressed to deter people from either inhaling it or injecting it, correct?

A. Yes.

Q. And it doesn't deter you from -- you can abuse reformulated OxyContin just by swallowing it, correct?

A. That's correct.

Q. Now, isn't it true, Dr. Fanelli, that most people don't abuse OxyContin by either inhaling it or injecting it?

A. The -- I'm not aware of the specific -- that's again part of that risk in the epidemiology group. I know we have data on that, but the early discussions with FDA were looking at ways to address, and this was one of the -- a first step in reformulation.

Q. But most people abuse OxyContin by taking it orally, correct, the majority of people do?

MR. SNAPP: Object to the form.

THE WITNESS: I don't know the exact numbers.

BY MR. CRUEGER:

Q. Have you ever looked at that issue?

A. Yes.

MR. CRUEGER: I'm going to hand you what's been labeled Exhibit 12.

(Document marked for identification as Exhibit Fanelli-12.)

BY MR. CRUEGER:

Q. And, Dr. Fanelli, this is a surveillance report prepared by Navippro, correct, or it's called a Navippro report?

A. Navippro, yes.

Q. And this one happens to be dated June of 2013, correct?

A. That's correct.

Q. Just briefly explain for me why Purdue was preparing or had these reports prepared?

MR. SNAPP: Object to the form.

THE WITNESS: So I'm not sure what this particular report was prepared for.

BY MR. CRUEGER:

Q. So let me ask it this way: Do you know why Purdue had this report prepared?

A. Not specifically for this particular report. We have -- Navippro is one of the studies in our postmarketing required studies, and we have -- we talked about it either today or yesterday, requirements to provide interim reports, so this could be -- but I'm not -- in this form without seeing cover

letters, I'm not that familiar with this particular report.

Q. Well, let's go to -- unfortunately they don't -- well, page 32 of 71 and Table 8, you see where we are?

A. Yes.

Q. And this report is giving percentages of people who abuse OxyContin, reformulated OxyContin and actually original OxyContin by different routes, oral, snorting, smoking, injecting and then other.

And this table would suggest that most people, the majority, who abuse OxyContin abuse it by just taking it orally, correct?

MR. SNAPP: Object to the form.

THE WITNESS: In the first column that's what it appears, yes.

BY MR. CRUEGER:

Q. Okay. Are you familiar at all with any of the patent litigation surrounding the ADF reformulation?

A. I know they exist, but I'm not familiar with them.

Q. Did you play any role in it

whatsoever?

A. You know --

MR. SNAPP: Object to the form.

THE WITNESS: I gave a deposition, but I can't recall if it was specific to OxyContin or around some other patent issue.

BY MR. CRUEGER:

Q. Were you involved at all in the -- I'm trying to think of how to ask this question so just --

A. Okay.

Q. Were you involved in how Purdue licensed the patents that it used for the abuse deterrent formulation in reformulated OxyContin?

A. No.

MR. CRUEGER: Okay. So let's just take a quick break.

THE VIDEOGRAPHER: The time is 2:50 p.m., going off the record.

(Brief recess.)

THE VIDEOGRAPHER: The time is 3:01 p.m., back on the record.

BY MR. CRUEGER:

Q. So let's just talk a little bit about the -- what happened after the FDA approved reformulated OxyContin or actually also when it approved it.

So the approval was -- if you remember, it was April 16th, 2013, correct?

A. I don't have it -- I believe that's correct.

MR. SNAPP: Did you say 2013?

THE WITNESS: Was it '12?

MR. CRUEGER: Well, approval -- I'm sorry.

BY MR. CRUEGER:

Q. It was approved in 2010, correct?

A. Yeah, yeah, sorry.

Q. And then the FDA did not approve a label change in 2010, correct?

A. There was no label change at that time.

Q. And the FDA asked -- either asked or required, I'm not sure which word you want to use, that Purdue conduct further studies about the abuse deterrent formulation and its effectiveness, correct?

A. Yes.
Q. And Purdue did a series of studies, correct?
A. And continued to do those studies, yes.
Q. Right, but it did a series of studies and it submitted it to the FDA, correct?
A. Yes.
Q. And then on April 16th, 2013 is when the FDA approved the label change, correct?
A. Correct.
Q. And at the same time that it approved the label change, it also withdrew the approval for original OxyContin, correct?
A. I don't -- subsequently, they did, but I don't know if it was -- I don't believe it was at the same time.
Q. For our purposes, whether it was the same day or not, it doesn't matter, but after it approved the label change, it also withdrew the approval for original OxyContin, correct?
A. That's correct.
Q. And then it also stopped

accepting abbreviated new drug applications, correct?

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. For original OxyContin?

A. That's correct.

Q. And that means that a generic manufacturer could not file an abbreviated new drug application to sell original OxyContin, correct?

A. Yes.

Q. Okay. Did the FDA approve any -- or grant any exclusivity period for reformulated OxyContin?

A. I'm not familiar with the exclusivity based on that.

Q. Does reformulated Oxycontin have any exclusivity, FDA exclusivity, period?

A. It's past the nonpatent exclusivity for a -- that's a three-year, if clinical trials are required, it would be patent exclusivity.

Q. And then the FDA also required more -- that Purdue do additional studies on the

effect of abuse deterrence -- of the abuse deterrent formulation?

A. Correct.

Q. And it was trying -- to summarize it all up, it was trying to -- what Purdue was trying to demonstrate was that the abuse deterrent formulation actually reduced abuse in the communities, correct?

A. Correct.

Q. And Purdue then commissioned a series of studies to be carried out to study that, correct?

A. Yes.

Q. Okay. By the way, I'm going to ask you, so starting in 2010 Purdue Pharma or Purdue was only selling reformulated OxyContin, correct?

A. There was a transition from the original to the reformulated.

Q. So as of, like, 2011 then, let's say, as of 2011, Purdue is only selling reformulated Oxycontin?

A. Yes, we are distributing the reformulated version.

Q. Isn't distributing the same as selling?

A. Yes.

MR. CRUEGER: Okay. So I'm going to give you what has been marked Exhibit 13.

(Document marked for identification as Exhibit Fanelli-13.)

BY MR. CRUEGER:

Q. And, again, just tell me when you're done reading it.

A. (Witness reviews document.)

I finished.

Q. Okay. So this is an e-mail to you from Todd Baumgartner?

A. Correct.

Q. Who is that?

A. Baumgartner, he was -- I have to look at the year. 2012, he was -- I believe he was the head of regulatory affairs at the time. At one time he was head of regulatory affairs, then he was the head of all of R&D, so I reported to him in both capacities.

Q. He worked for Purdue --

A. A couple times.

Q. He worked for Purdue Pharma?

A. Yes, sorry.

Q. Okay. And the subject line TR IR opioids, can you explain what that means?

A. Tamper-resistant immediate-release opioids.

Q. And if you look at what he -- after having my initial thoughts and then he has like thought 5 and thought 7, I'm not sure what happened to 1 through 4 or 6, but number 7 is what I'm a little bit interested in, so it says "recall we had actively discouraged Rhodes from launching a generic IR Oxycodone." I'm not going to continue reading.

Rhodes is Rhodes Pharmaceuticals?

A. Correct.

Q. And what is it referring to in that you had -- when he says "we had actively discouraged Rhodes from launching their generic IR Oxycodone"?

MR. SNAPP: Object to the form.

THE WITNESS: I don't -- I don't recall right now what that discussion

was.

BY MR. CRUEGER:

Q. So Rhodes Pharmaceuticals they -- IR -- strike that.

IR Oxycodone, that refers to immediate release?

A. Correct.

Q. And Rhodes Pharmaceuticals is selling immediate-release Oxycodone?

MR. SNAPP: Object to the form.

THE WITNESS: I believe they are, yes.

BY MR. CRUEGER:

Q. And they sell it as a generic, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MR. CRUEGER:

Q. And was there a concern about Purdue selling a reformulated abuse deterrent OxyContin and at the same time having a Purdue-affiliated company selling an immediate-release generic Oxycodone product?

MR. SNAPP: Object to the form.

THE WITNESS: There were discussions about that.

BY MR. CRUEGER:

Q. And what were the discussions?

A. We had a tamper-resistant project in development. Unfortunately, we were unsuccessful in developing that project, but we felt that that was an important product, if we could meet the FDA's requirements, to get it on the market, and that would be preferred.

Q. Well, first of all, who is "we," Purdue Pharma?

A. Yeah.

Q. And when you say a tamper-resistant product, are you talking about a tamper-resistant, immediate-release?

A. Yes, I'm sorry.

Q. Yeah, a tamper-resistant, immediate-release product, correct?

A. Correct.

Q. And you, Purdue, were trying to develop that immediate-release, tamper-resistant product for Rhodes Pharmaceuticals to sell?

MR. SNAPP: Object to the form.

THE WITNESS: No. I don't have the agenda for that meeting, it's not attached, but we were studying it and actually have submit -- did submit the application, the name was Ovreedy(ph.) for an abuse deterrent IR formulation.

BY MR. CRUEGER:

Q. Of?

A. Of oxycodone, sorry.

Q. Just to back up quickly, you said you don't have the agenda that's attached. Is it just one page?

A. Yeah. Well, there's two -- there's nothing on this page.

(Document marked for identification as Exhibit Fanelli-14.)

BY MR. CRUEGER:

Q. I only have one copy, obviously. Is this the agenda for that e-mail, what's been labeled Exhibit 14?

A. (Witness reviews document.) I've reviewed it, so I see it.

Q. I was just asking is that the agenda that's supposed to be attached to Exhibit

13?

A. It appears to be.

Q. Okay. So back to Exhibit 13, in that paragraph 7 it says -- he writes, "But, now, if we clearly are trying to bring forward a TR IR formulation (and thus trying to address the problem), I see no reason why we need to be secretive."

What is he referring to there about being secretive?

MR. SNAPP: Object to the form.

THE WITNESS: I don't recall.

BY MR. CRUEGER:

Q. And is Rhodes Pharmaceuticals, is it currently selling an immediate-release Oxycodone product?

MR. SNAPP: Object to the form.

THE WITNESS: I believe they are.

BY MR. CRUEGER:

Q. Do they have -- does Rhodes Pharmaceuticals sell a tamper-resistant Oxycodone product?

A. No.

Q. And, again, Rhodes

Pharmaceuticals, it's really owned by the same family, the Sackler family, as Purdue, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not aware of the ownership of the different corporations.

BY MR. CRUEGER:

Q. You think someone else other than the Purdue family controls either directly or indirectly Rhodes Pharmaceuticals?

MR. SNAPP: Object to the form.

THE WITNESS: Again, I don't know the ownership.

BY MR. CRUEGER:

Q. How long has Rhodes Pharmaceutical existed?

MR. SNAPP: Object to the form.

THE WITNESS: I do not know.

BY MR. CRUEGER:

Q. But you occasionally have e-mails like this about Rhodes Pharmaceuticals, correct?

A. Yes.

Q. Did you just assume it was an independent third company that had no

affiliation or association with Purdue?

MR. SNAPP: Object to the form.

THE WITNESS: No. We consider it an independent associated company is how we term it.

BY MR. CRUEGER:

Q. And what does that mean in reality? What is an independent associated company?

A. So, again, this would be more details from our law department, but it's not the same -- my understanding is it's not the same company, different legal and corporate entity, but I'm not -- I don't have that background to address that.

Q. Does Purdue sell any immediate-release Oxycodone products?

A. No.

Q. Does Purdue sell any -- well, answer if you --

A. No, we don't currently, that's correct.

Q. Did Purdue at one time while you've been at Purdue since 2000 sell an

immediate-release Oxycodone product?

A. Oh, Dilaudid is hydromorphone, so no.

Q. Okay. Does Purdue sell any of the drugs that are used to treat opioid addiction?

A. No.

Q. Purdue doesn't sell any drugs that are used to treat opioid addiction?

A. Currently, no, that I'm aware of.

Q. How about Rhodes Pharmaceuticals?

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. Does Rhodes Pharmaceuticals sell any drugs that are used to treat opioid addiction?

MR. SNAPP: Object to the form.

THE WITNESS: I don't know Rhodes -- all of Rhodes' products.

BY MR. CRUEGER:

Q. Okay. So before we got on this little tangent, we were talking about the ADF and reformulated OxyContin. We had just talked about the April 16th, 2013 FDA approval of the

new label for the abuse deterrent formulation and that the FDA had asked or required Purdue to do additional studies about the abuse deterrent formulation, correct? You kind of remember that's where we were?

A. Yes.

Q. Okay. And Purdue did those studies, correct?

A. We're currently conducting those studies.

Q. And it would submit --

(Document marked for identification as Exhibit Fanelli-15.)

BY MR. CRUEGER:

Q. I'll just pass you what's been labeled Exhibit 15.

So Exhibit 15 is a document entitled "Overview and Interpretation of the Post-Marketing Program to Assess the Effects of Reformulated OxyContin on Opioid Abuse in 3 Formal Studies, 1 Drug Utilization Study, and Contextual Studies," and it's dated September 2014.

Are you familiar with this study

or this -- this document, actually?

A. I'd have to get -- I'm vaguely familiar with it. It appears to be -- we talked about earlier postmarketing requirements have update requirements, and this could be one of those, but I'm not sure. I'd have to look at it.

Q. Do you understand why Purdue filed this document with the FDA? Let's just start, did Purdue file this document with the FDA?

A. This particular one? I'd have to -- if there was a cover letter that accompanied this, I'd know whether this was the version that went to FDA. If you notice, it says a study reported in July 2012 report. This appears to be the next update, but I'm not -- without seeing additional documentation, I'm not certain, but that's what it appears to be.

Q. Did you have any involvement while you were at Purdue in submitting these studies or these reports to the FDA?

A. Yes.

Q. Okay. And assuming that this was

submitted to the FDA, can you explain just at a very general high overview Purdue's purpose for submitting this 2014 report?

A. Yeah, as I stated previously, the postmarketing required studies, FDA gives time months for submitting of the proposals, interim reports and final study reports. This would -- could satisfy submitting one of those interim reports.

Q. So but what -- what Purdue is trying to do with this submission is report to the FDA its view of what these studies are showing on whether the abuse deterrent formulation is effective at reducing abuse, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It's submitting an interim report on the status of our investigations. It talks here about three formal studies, a drug utilization study and contextual study, so it's a number of studies, and this is an update report on the current status of those, as required.

BY MR. CRUEGER:

Q. And so if you look at page 5 quickly --

A. Five by the report number.

Q. Five by the actual page numbers, yes.

A. Yeah.

Q. And there's a paragraph or Section 1.4 Conclusions.

A. Yes.

Q. And just the first sentence, "These findings indicate that abuse of OxyContin decreased substantially after reformulation and that these decreases have persisted up to three years post-reformulation," correct? That's what -- that's what that sentence says?

A. Yes.

Q. And that is what Purdue is telling the FDA, correct?

MR. SNAPP: Object to the form.

THE WITNESS: That a conclusion in an interim report about what the findings indicate.

(Document marked for

identification as Exhibit Fanelli-16.)

BY MR. CRUEGER:

Q. So, Dr. Fanelli, what I've handed you is Exhibit 16. Don't worry, we are not going to parse through and read this thing. I'm just ask -- actually, the only reason I'm even giving it to you is just to ask you if, first of all, if you can tell me, have you seen this document before?

A. Yes.

Q. And can you tell me what the document is?

A. This is a FDA briefing document prepared prior to a scheduled advisory committee meeting.

Q. And what is the briefing document about?

A. The advisory committee -- it was a joint advisory committee. I think we talked about this yesterday, DSaRM is the safety group, and AADPAC is the anesthesia group, Sharon Hertz is the head of that FDA division, but this is -- those are the advisory committees, and it was to discuss whether the reformulated OxyContin --

what the -- what the outcomes of those were, of the reformulation.

Q. And you received this document, correct?

A. Yes.

(Document marked for identification as Exhibit Fanelli-17.)

BY MR. CRUEGER:

Q. So I'm going to hand you what is 17.

MR. SNAPP: Are we done with 16?

MR. CRUEGER: Yes.

MR. SNAPP: Thank you.

BY MR. CRUEGER:

Q. And so that briefing document that was Exhibit 16, obviously, you and other people at Purdue had read through that document, correct?

A. Yes.

Q. And you read through it because you were going to have a meeting with the FDA on July 7th and 8th of 2015, correct?

A. Yes.

Q. And just from reading this

e-mail, is it safe to say that the FDA was not persuaded by the evidence that Purdue had produced so far that the reformulated OxyContin had reduced abuse in the community?

MR. SNAPP: Object to the form.

THE WITNESS: What I would say is briefing documents, and it says so, and FDA said so, are the views of the individual reviewers from the different sections and that they're mentioned here, the epidemiologic, the statistician, and they're up for -- they're not a -- they're not a conclusion of FDA, per se, but it's providing reviews for the advisory committee's view to look at.

BY MR. CRUEGER:

Q. And these reviews, from Purdue's standpoint, were generally negative, correct?

MR. SNAPP: Object to the form.

THE WITNESS: There were statements in there, yes, that we believed would require more work for us to address.

BY MR. CRUEGER:

Q. And that's this Exhibit 17, this is an e-mail -- originally, it's actually two e-mails. Originally, there is an e-mail that seems to be from you, although it doesn't say who -- who exactly it went to, correct? It starts with the line that's on June 23rd, 2015?

A. Yes.

Q. So from that on downward, that's the e-mail that you wrote, correct?

A. Correct.

Q. And without going through them, you had just highlighted a few quotes that you took out of what is Exhibit 16, correct?

A. Yes.

Q. And you sent them to Gail, if you could pronounce her name correctly.

A. Her name is Dr. Gail Cawkwell.

Q. Okay. And her reaction was "sigh," correct?

A. That's what it says.

(Document marked for identification as Exhibit Fanelli-18.)

BY MR. CRUEGER:

Q. I'll hand you what's Exhibit 18. You don't actually have to read through this document. I'm not going to ask you about all the contents. I'm more interested in just a few parts of it, okay.

A. I just want to see what it is.

Q. Sure. Oh, feel free to read it.

A. Okay.

Q. I'm actually just more interested in the first what is the -- it says, "dear EC members." Before we get into that, this is an e-mail from Gail Cawkwell to various people, and it CCs you and other Purdue employees, correct?

A. Correct.

Q. And it attached that FDA briefing document, that would be Exhibit 16, correct?

A. So it states there, yes.

Q. And it says -- what I'm interested it says, "dear EC members," what is the EC?

A. The executive committee -- stands for the executive committee.

Q. Okay. And what is the executive committee?

A. The to -- on the to line you see the members of the executive committee.
Q. Okay. And but what does the executive committee do?
A. Oh, it's heads of departments.
Q. Okay. Heads of departments in Purdue?
A. Across Purdue.
Q. Okay. And who is Stuart Baker?
A. Stuart Baker, I'm not sure of his title, he was a member of the executive committee.
Q. Is he a Purdue employee?
A. I'm not -- I believe he is. I'm not sure. He is an executive. Purdue has -- well, he's at Purdue.
Q. He's at Purdue?
A. Yes.
Q. So I'm just a little -- I just want to -- is everyone in this to line on the executive committee, are they all Purdue employees?
A. I don't know if Stuart has -- is an outside attorney or could be, I don't know

him that well.

Q. Okay.

A. I was not a member of the committee, but I know Stuart and everyone else, yeah, on the to line, they make up the executive committee.

Q. So you know Stuart, but you're not quite sure if he's a Purdue employee?

A. Yes, I don't -- I don't know his -- he works for the executives and the board. I don't know what his title.

Q. Who does the executive committee report to?

A. The CEO, who is also listed on here. At the time it was Mark Timney.

Q. Do you know if the briefing document, if it was sent to any of the owners of Purdue Pharma, the Sackler family?

MR. SNAPP: Object to the form.

THE WITNESS: I am not aware.

BY MR. CRUEGER:

Q. I'm sorry. I didn't under -- I didn't hear your answer to the question.

A. I apologize. I do not know.

(Document marked for identification as Exhibit Fanelli-19.)

BY MR. CRUEGER:

Q. Sir, you've been handed Exhibit 19. This is an e-mail from you to Matthew Sullivan, correct?

A. Yes.

Q. And it's June 26, 2015, correct?

A. Yes.

Q. And the subject is Purdue's decision on OxyContin SDNA?

A. SNDA.

Q. SNDA, and then it's a number, S-026.

Just can you just quickly explain what an SNDA is?

A. Sure. It's a supplemental new drug application. Once a drug is approved the first time, that's the NDA and any changes, significant changes, of course, and this was supplement -- FDA makes the identification supplement number 26 for the OxyContin NDA.

Q. And does supplement number 26 have anything to do with the abuse deterrent

formulation?

A. It did.

Q. And what was it?

A. This supplement was a labeling supplement to add the results that we've been talking about of the postmarketing studies after the change to the label with the data.

Q. So Purdue wanted to change the label to add information -- strike that.

Purdue wanted to change the label to add a statement that reformulated OxyContin reduced abuse in the community?

MR. SNAPP: Object to the form.

THE WITNESS: So that -- FDA has a guidance on information about opioids in a label. I don't know if you want me to go into this, I'll just very briefly. The ones that you talked about first approval with the labeling, those were premarket studies, category 1 and category 3, which are testing for extraction, that's one. Three is abuse liability studies, and FDA guidance is pretty clear, and there are now I don't

know how many current today opioids. There are numbers of them.

The last category, there's no drug yet approved with category 4 it's called, which is the real world data, and that's what this was.

BY MR. CRUEGER:

Q. And what would that -- practically, how would that change the label for the drug?

A. So there's a section, section 9 which talks about the abuse liability and evidence, especially on these -- well, it's in many drugs, a lot of classes, but for the opioids, especially the abuse deterrent ones, it describes the results of those studies.

Q. And that SNDA number 26 and the studies, that's what we're referring to here in this -- with this Exhibit 16, that FDA briefing document, that's what that's talking about, correct?

A. Correct.

Q. And to sum up this e-mail that you're sending to Matthew Sullivan, Matthew is

at the -- Matthew Sullivan is an FDA employee?

A. He's a project manager in Dr. Hertz's division.

Q. And it's canceling the meeting that you were going to have with the FDA on I guess July 7th and 8th, 2015?

A. It's withdrawing the supplement is what this is about.

Q. Does that also cancel the meeting then?

A. Yes.

Q. And who made the decision to withdraw the supplement?

A. It was a decision -- I think the executive committee, maybe not all members. I don't remember who made -- you know, who was involved in that but members of the executive committee.

Q. Was it your decision?

A. Not alone.

Q. Were you involved in the decision?

A. Yes.

Q. Do you know what the basis for

the decision was to withdraw the application?

A. Yes.

Q. What was it?

A. Based on -- and you see it also talks about having a discussion with Dr. Hertz and Dr. Staffa at FDA. Based on their review of the data and it was clear that more work had to be done prior to changing of the label. So the discussions were around continuing that work to address those limitations that they pointed out.

Q. Now, this -- Purdue's efforts on this abuse deterrent formulation and working with the FDA, is this a -- does Purdue view abuse deterrent formulation as a way -- as a way to keep out generics?

A. The goal of the abuse deterrent formulation is to address the abuse of the product.

Q. And Purdue would like to be able to use the abuse deterrent formulation in its marketing?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not sure what you mean by "marketing."

BY MR. CRUEGER:

Q. Do you know whether Purdue wants to use any of the abuse deterrent formulation -- strike that.

Do you know whether Purdue wants to use the ADF in its marketing to sell OxyContin?

MR. SNAPP: Object to the form.

THE WITNESS: Currently, we don't have a sales force and we are not using them in the promotion of our products.

BY MR. CRUEGER:

Q. I guess my question is are you using this abuse deterrent -- are you using the abuse deterrent label in any way to sell the product that you know of?

MR. SNAPP: Object to the form.

THE WITNESS: The abuse deterrent was designed to address issues around misuse/abuse, and that's the goal, and that's why we're commercializing it as an abuse deterrent.

BY MR. CRUEGER:

Q. And are you aware whether Purdue

is trying to use the abuse deterrent formulation to limit generic competition?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not aware of anything like that.

MR. CRUEGER: Just give you what's labeled Exhibit 20.

(Document marked for identification as Exhibit Fanelli-20.)

BY MR. CRUEGER:

Q. By the way, Purdue sells what's often referred to as branded drugs, correct?

A. Yes.

Q. So and what that means is OxyContin is a branded drug, correct?

A. I would -- yes.

Q. And Purdue does not sell -- Purdue Pharma does not sell generics, correct?

A. Correct, currently.

Q. And as a branded -- a distributor of a branded product, Purdue would like to limit generic competition, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I have no answer to

that.

BY MR. CRUEGER:

Q. Well, you were at Purdue in 2004 when it lost patent protection on original OxyContin, correct?

A. Correct.

Q. And that had a substantial negative impact on Purdue, correct?

A. Correct.

Q. Because it allowed generics to come into the market and compete against Purdue, correct?

MR. SNAPP: Object to the form.

THE WITNESS: It resulted in a reduction in the sale of the branded product, yes.

BY MR. CRUEGER:

Q. Right, from generic competition, correct?

A. Yes.

Q. And do you know what Purdue sales of OxyContin, original formulated OxyContin were prior to it losing patent protection?

A. I don't know the numbers.

Q. Was it around $2 billion?
MR. SNAPP: Object to the form.
THE WITNESS: It might have been. It was something like that.
BY MR. CRUEGER:
Q. And then it went down to -- with generic competition after about a year, it was down to about 6 or $700 million?
MR. SNAPP: Object to the form.
THE WITNESS: I don't know the exact number, but it was a significant reduction.
BY MR. CRUEGER:
Q. And it resulted in layoffs at Purdue?
A. Correct.
Q. A reduction of the sales force, correct?
A. I'm not part of that business. I believe so, but I don't know what happened in other areas outside of my area.
Q. And just really the whole point of this is generic competition doesn't really -- is something Purdue would like to avoid,

correct?

MR. SNAPP: Object to the form.

THE WITNESS: It's not part of our business.

BY MR. CRUEGER:

Q. Well, I don't think someone competing against you is part of anyone's business.

What I'm saying is you would -- you, Purdue, would not want generics to compete against reformulated OxyContin, correct?

MR. SNAPP: Object to the form.

THE WITNESS: There are, based on exclusivity, we would -- yes, that's important that those are maintained, the exclusivity.

BY MR. CRUEGER:

Q. So going back to this Exhibit 20 that I handed you, it's a 2015 e-mail.

A. Correct. 2015, yeah.

Q. The e-mail that's interesting is the one that you sent to Douglas Throckmorton.

A. That's correct.

Q. And he's at FDA, correct?

A. Correct.

Q. And the e-mail just summarizes -- it sounds like a discussion and some points that you wanted to put in writing to convey to the FDA, correct?

A. Correct.

Q. And I just wondering a little bit about what some of those points are.

So one of them is the clarification of the scope of ADF exclusivity, it's the second point you make.

Do you see that?

A. Yes.

Q. Can you explain what you're really talking about there?

A. Sure. So this was a meeting about opioid abuse deterrents with -- I can't remember all the attendees from FDA side, but Gail Cawkwell, Robin Abrams and myself with FDA, including Dr. Throckmorton, and we discussed a number of topics.

That particular one, FDA has made statements, recently as well, about the value of abuse deterrents in this class of drugs and has

made statements about exclusivity around those properties.

Q. In other words, to boil all that down when we're talking about exclusivity, that means the FDA would grant some sort of exclusivity to limit generic competition for an ADF formulation?

MR. SNAPP: Object to the form.

THE WITNESS: So products get -- we talked about that I think yesterday -- get exclusivity based on products, class and supplements, you know, the nature of the data in order to incentivize doing that work, and that's what that discussion was.

BY MR. CRUEGER:

Q. But again, I just want to make sure I understand what you're saying, because I think the -- isn't the perhaps more blunt but concise way of saying it is you want exclusivity for developing the abuse deterrent formulation?

MR. SNAPP: Object to the form.

THE WITNESS: Correct.

BY MR. CRUEGER:

Q. Well, the points aren't numbered, it's the point that starts with "class-wide."

You see where I am? It's third from the bottom, third point from the bottom.

A. Correct.

Q. So it says, "Class-wide immediate-release opioid labeling to reflect demonstrated substantial abuse and addiction risk of such products."

What did you mean by that?

A. So I don't have the -- a transcript of this, but these are some of the discussions that we had. I can't remember who brought it up first, but FDA actually has taken steps related to that. All of the IRs now have a boxed warning. They all are, as of very recently, changed the boxed warning and include statements about the REMS, and they're now part of the REMS, so that are the kinds of things that were discussed.

Q. And that's something that you wanted, that boxed warning?

A. We didn't get to specifics of, you know, to that level, but to point out that

there is substantial abuse of those immediate-release products.

Q. So what Purdue wanted and what you were conveying here is you wanted the label changed for immediate-release opioids to reflect a substantial abuse and addiction risk, correct?

A. No. There was a discussion -- as I said, I don't remember who brought it up or how it was brought up. This whole discussion, we've had two or three of them now that I've been involved in, meeting with FDA leadership about actions we're taking or ways to address, we talked about the opioid crisis, and that was one that we talked about was by increasing those warnings on IR products because of the amount of abuse that's in that -- those group of products would be beneficial to address that issue.

Q. So -- and your extended-release OxyContin product competes against the immediate-release products, correct?

MR. SNAPP: Object to the form.

THE WITNESS: The actual -- the labeling for OxyContin talks about a limitations of use that -- and we could

read it, but after -- OxyContin is only to be prescribed, at least as listed in the limitations of use, after other agents are tried and it includes immediate release.

BY MR. CRUEGER:

Q. Right, but after -- in the world of the market, one of the drugs that OxyContin extended-release or any extended-release product competes against would be an immediate-release product, correct?

MR. SNAPP: Object to the form.

THE WITNESS: So I don't know what you mean by "competes."

You know, prescribers make a determination whether an IR opiate is appropriate or an extended-release. They don't have the same indication, so they're not in the same class.

BY MR. CRUEGER:

Q. Well, would you agree, Dr. Fanelli, when I -- when I read through all the points that we're making, they all look like points that Purdue is discussing with the FDA to

in one way or other restrict people from competing with your reformulated OxyContin product?

A. No, that's not how --

MR. SNAPP: Object to the form.

THE WITNESS: Sorry.

These discussions with FDA did not include commercial discussions. They were all about addressing opiate abuse and what steps we could take to address that.

BY MR. CRUEGER:

Q. So what -- what is the branded industry working group?

A. So that's not the -- I'm not that -- I've heard of it, and without seeing documents, I can't remember which exact project that is.

Q. Do you have more than one like industry -- branded industry working group?

A. Yes.

Q. So what do they -- how many of them are there?

A. There -- the one that I'm -- the

regulatory representative for the branded industry is related to the class-wide PMR requirements, those 11 studies. I am the regulatory representative of all those companies to the FDA, FDA liaison function. So, as a matter of fact, I got an FDA e-mail that they want to talk to the brand -- but it -- so it depends on what you're talking about and what the timing is.

(Document marked for identification as Exhibit Fanelli-21.)

BY MR. CRUEGER:

Q. So this one seems to be about -- this Exhibit 21 that I've handed you --

A. Yes.

Q. -- this one is an evaluation of abuse deterrent properties of opioid drug products.

So that would be a different industry working group?

A. So -- yes. And I attended, I think I was on there, I know Purdue had representation, I don't know if it was myself or Todd, I know about it.

FDA had a public meeting about evaluation of the abuse deterrent properties of opiate drugs. We talked about there are guidances that are out there about the different categories of studies. This is looking at premarket evaluation, how those studies are conducted. And, actually, the guidance for the branded products was already out there. FDA had made public statements that they were going to be providing abuse deterrent guidance for the generic products as well so that to help those products know what they needed to do to get approval.

Q. So I just noticed this isn't Bates numbered, so it must have come from a native file, so we'll have to get the Bates number for it, but -- so if you go to I think it's page 10 it says "OD Opioid Development: Category 1 Studies" at the top.

A. Yes, I'm on that page.

Q. About -- it's closer to the bottom, it's actually, it's a point that's above formulation plus process equals AD characteristics, there's a -- like a double

indented subpoint there.

A. Yes.

Q. Do you see that?

A. I think so, yeah. It starts with "risk."

Q. So "risk of approving generic AD products would non-equivalent abuse deterrent properties."

What risk is this referring to?

MR. SNAPP: Object to the form.

THE WITNESS: Again, we talked about category 1 studies. Those are studies that in vitro testing, looking at different solutions, whether in a test tube, you could extract the agent and although -- I believe although, again, it's been a while, and I didn't write this particular statement, but I was -- I can't remember if I was at the meeting or read the transcripts, but the issue there was if a generic drug -- if the branded drug has certain abuse deterrent properties demonstrated by those studies, it would be important

that a generic of that drug had at least the same abuse deterrents, and FDA has now, as a matter of fact, in a recent advisory committee looking at not generics but branded products in a similar -- for a similar molecule and are evaluating the same.

It's difficult to do because, you know, these different studies and they have different technologies, you talked about hardness, and there's different technologies, and there's -- there was a statement that would be important that a generic is at least as abuse deterrent as the brand.

Q. And so that would be a standard that a generic would have to meet before it could get approval, correct?

MR. SNAPP: Object to the form.

THE WITNESS: This was a discussion of what should be in that guidance, and that was talking about that, yes.

BY MR. CRUEGER:

Q. And then if you go to the fifth page it says "Public Health Imperative."

A. Back to the front five, okay.

Q. And so just -- so this is the -- an industry group presentation to the FDA, correct?

A. Correct.

Q. And it's Purdue and it's all the other companies that are listed on page 2. I'm not going to read them off.

A. I see that, yes.

Q. And on this page it talks about the "opioid epidemic requires action from multiple stakeholders to address the crisis," correct?

A. Yeah, I'd like to point out on page 2 there's a statement at the bottom, the views expressed in this presentation represent the best available consensus of the branded industry working group as a whole. So remember this was a public meeting where there was discussion of these topics. These are views -- it's not each of those companies did not sign off on each of these views, but just to put that

in context.

Q. But there seems to be a consensus at least on what's in this PowerPoint, correct?

A. That's what -- yes, that's how it was designed.

Q. And so there's also then a consensus on actions that are required to address the crisis, correct?

A. There are some statements in here addressing that, but that wasn't the focus of the meeting.

Q. No, but they're in the PowerPoint, correct?

A. Yes.

Q. And so there's a consensus on what an FDA opioid action plan, correct?

A. That's stated there, yes.

Q. And then there's a consensus on treating the problem, what's needed to treat the problem, correct?

A. Mm-hmm.

Q. And this includes medicated -- medication assisted therapy for addiction, correct?

A. Mm-hmm, yes.

Q. And then the third part, and so -- so just actually -- so does the FDA -- there's treatment is another way to remedy the problem, correct?

A. Yes.

Q. And then the third part of this prong supposedly is abuse deterrent opioids, correct?

A. That's the third listed here.

Q. Right. And that's just one -- it even says in here it's just one component of this multi-faceted approach, correct?

A. Yes.

MR. CRUEGER: Just for the record, so Exhibit 21 was produced to us as Bates number PPLPC01600319013, and it was labeled highly confidential, subject to protective order. If you just want to take a quick break, and then we'll come back and wrap it all up.

THE VIDEOGRAPHER: All right. The time is 4:04 p.m., going off the record.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:22 p.m.

BY MR. CRUEGER:

Q. Dr. Fanelli, we're looking at Exhibit 15. You have that in front of you, correct?

A. I do.

Q. If you turn to page 45, and before I ask you any questions, this document is -- this was prepared by Purdue, correct?

A. I believe so. I don't see any author, and we talked about that earlier, I don't see the cover for this. It has a demarcation of our NDA, so either by Purdue or for Purdue.

Q. Okay. If you go to page 45, that's paragraph 3.13. It's called "Prescribing Patterns Among Potentially High Risk Prescribers."

Do you see me, where I'm at?

A. Yes, I see.

Q. The first sentence starts with "using IMS Exponent data."

Do you know what IMS Exponent data is?

A. I do not. I know what IMS is, but I don't know what Exponent data are.

Q. So what is IMS?

A. It's a -- I guess it's a business, I'm not even that aware of what their -- my understanding is they provide to prescription -- or to pharmaceutical companies data about prescription of their products.

Q. So but what can happen is a company like Purdue can go to IMS and buy data about prescriptions that are being written for OxyContin, for example?

A. That's my --

MR. SNAPP: Object to the form.

THE WITNESS: That's my understanding.

BY MR. CRUEGER:

Q. Okay. And if you could quickly read that section, so I can just ask you questions about it, this page 45 to 46.

A. (Witness reviews document.)

Those two pages, yeah.

Q. Yes.
A. So I finished.
Q. So just to try to quickly summarize what this is, this is Purdue is trying to show a benefit of its reformulated OxyContin drug, correct?
MR. SNAPP: Object to the form.
THE WITNESS: What we're reporting on are data that we have. I don't even know -- results that we have on investigations we were doing around the abuse deterrence, and these are the data.
BY MR. CRUEGER:
Q. And so what Purdue did is it went out and it purchased the data about the prescription practices of 321 doctors who they've identified as engaging in potentially suspicious or questionable prescribing, correct?
MR. SNAPP: Object to the form.
THE WITNESS: I'm not -- this is a summary. I'm not that familiar with the details to this level. Oh, I see where you quoted the number. I see that

now, that's what it states, yes, 312.

BY MR. CRUEGER:

Q. And it's -- what Purdue has done is it's purchased the data to show the prescribing practices of these 321 doctors in prescribing 80-milligram OxyContin, correct, the graph on page 46?

MR. SNAPP: Object to the form.

THE WITNESS: So what that graph -- as I'm seeing this, I don't remember seeing this report that we're talking about. It looks like reports over time related to the OxyContin reformulation, yes.

BY MR. CRUEGER:

Q. And what Purdue is doing is they're showing the change in prescriptions for 80-milligram OxyContin to prescriptions of 40-milligram Opana ER, correct?

A. Those are the two graphs there, yes.

Q. And what it's showing is that when Purdue introduced the reformulated OxyContin, it showed a drop in prescriptions of

80-milligram OxyContin by these identified -- these 321 prescribers, correct?

A. Yes.

Q. And at the same time it shows an increase in prescriptions by these same prescribers of the Opana ER 40-milligram, correct?

A. That's what's shown on that graph, yes.

Q. And the inference that is -- one of the inferences, would you agree that Purdue wants to be drawn from this -- these two graphs is that these doctors stop prescribing reformulated OxyContin because of the reformulation, correct?

MR. SNAPP: Object to the form.

THE WITNESS: Again, this is an interim report, but what it states there, these reserve changes are consistent with reduced diversion following the introduction of the reformulation.

BY MR. CRUEGER:

Q. Well, that's what's interesting,

so it's showing -- these are really two graphs about diversion; are they not?

A. It's a trend of prescriptions.

Q. But they're a trend of prescriptions among prescribers that Purdue has identified as engaging in suspicious or questionable prescribing activities, correct?

A. Correct.

Q. And it shows a reduction in OxyContin once reformulated OxyContin is introduced, correct?

A. Yes.

Q. And it shows a corresponding increase in Opana ER 40-milligram prescriptions, correct?

A. There is an increase of Opana.

Q. And so isn't this just Purdue showing how it can actually track, if it really wants to, suspected diversion at the prescriber level?

MR. SNAPP: Object to the form.

THE WITNESS: So, again, this is -- there are a number of studies, and, as we talked about a little while

ago, each has their limitations, has to be interpreted based on those limitations, but this is part of the data that's presented and --

BY MR. CRUEGER:

Q. Do you know if -- do you know if Purdue shared any of this data and information with state or federal law enforcement?

A. I'm not aware of that, whether or not.

(Document marked for identification as Exhibit Fanelli-22.)

BY MR. CRUEGER:

Q. I'll just hand you what's labeled Exhibit 22.

A. Oh, sorry, I got it.

Q. So the e-mail, in general, they're referring to Grunenthal, and that's a German company that Purdue licensed patents that cover some of the ADF technology, correct?

A. Yes. I'm not that familiar with those patents, but I've -- that's my understanding as well.

Q. And McGinity, is that -- that's

another patent that Purdue licensed, correct?

A. That's my understanding.

Q. It's referred to commonly as the University of Texas patent?

A. I'm not aware of that.

Q. What I'm interested in is they're talking about -- talking about maybe that Rhodes would also license the patents, correct?

A. So there's discussion of that. I have never -- I don't recall ever -- I'm not copied on this e-mail and wouldn't be. These kinds of conversations, discussions are not part of regulatory.

Q. I'm actually not even going to ask you about the licensing.

A. Okay.

Q. I'm actually going to ask you, it says in the middle of this e-mail, it says, "I encouraged them to talk to Jon Sackler before they conclude."

Do you see what I'm reading on the cover page?

A. On the first page, yeah.

Q. Who is Jon Sackler?

MR. SNAPP: Object to the form.
THE WITNESS: He's, I believe, although has been, I think, a board member, but, again, I don't -- that's where I -- my interactions with Jon Sackler have been is at board meetings.
BY MR. CRUEGER:
Q. So he's a member of the Sackler family?
A. Yes.
Q. Does he play an active role in Purdue Pharma?
MR. SNAPP: Object to the form.
BY MR. CRUEGER:
Q. That you're aware of?
MR. SNAPP: Object to the form.
THE WITNESS: He's at board meetings where they make decisions, yes.
BY MR. CRUEGER:
Q. Does he have an office at Purdue Pharma?
MR. SNAPP: Object to the form.
THE WITNESS: I'm not sure.
BY MR. CRUEGER:

Q. In your role, you work with attorneys a lot at Purdue Pharma?

A. I don't know what you mean by "a lot," but we talked about MRL, so medical, regulatory and law, so there are law individuals on the teams reviewing material, for instance. There's a regulatory attorney who is part of project team, so I do work with the law department.

Q. And I don't know if you would know, but there's approximately 5,000 plus e-mails of yours that have been designated as confi -- as withheld under the attorney-client privilege.

What's your understanding of the attorney-client privilege?

MR. SNAPP: Object to the form.

THE WITNESS: I don't have a -- I understand that it's related to confidentiality between attorney and client, but that's the extent of it.

BY MR. CRUEGER:

Q. And when do you include an attorney on an e-mail and when do you not?

MR. SNAPP: Object to the form.

BY MR. CRUEGER:

Q. Is there any sort of --

A. It would depend on the project.

Q. Did you have any guidance or training on when to include attorneys on e-mails and when not?

A. I would include attorneys -- for instance, we talked about it, if they're part of the project that I'm dealing with. They would be included -- there are attorneys on the -- the executive committee we talked about, so that's when they would be included.

Q. And do a lot of the attorneys that you do work with, are they actually more in the area of giving you business advice, or is it legal advice, or is it a mix of the two?

MR. SNAPP: Object to the form.

THE WITNESS: Not business -- what do you mean by "business advice"?

BY MR. CRUEGER:

Q. Well, what would you mean by legal advice? I mean, isn't -- you have to know the difference between the two, don't you?

MR. SNAPP: Object to the form.

THE WITNESS: The advice that I get is related to laws and regulations around development and approval of products, so that's what it would be about.

MR. CRUEGER: Okay. I have no further questions.

THE VIDEOGRAPHER: Off the record?

MR. CRUEGER: Yes.

THE VIDEOGRAPHER: Stand by. The time is 4:38 p.m., off the record.

(Pause.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:45 p.m.

BY MR. STEWART:

Q. Dr. Fanelli, you said moments ago that you had interactions with Jon Sackler at Purdue board meetings.

Do you recall that?

A. Jon Sackler was present at board meetings, yes, that I would see --

Q. That's when you would interact

with him?

A. Yes.

Q. And how many Purdue board meetings do you think you've spoken at or presented at in your career at Purdue?

A. It would be a very rough guess, a dozen maybe.

Q. Do Purdue board meetings, do they take minutes?

A. Do they --

Q. Do they take minutes of proceedings?

MR. SNAPP: Object to the form.

THE WITNESS: Not that I have been given.

BY MR. STEWART:

Q. Okay. You just don't know?

A. I don't know.

Q. Are board meetings recorded that you know?

A. I don't know.

Q. In some of the dozen -- estimated dozen times you've been before the board, have you given written presentations, brought

materials?

A. A few times, slide decks.

Q. Okay. Have you given any presentations to the board related to OxyContin?

A. Not that I recall.

Q. Do you think you'd recall that?

A. I wouldn't have been specifically OxyContin. It might have been on talking about something in general of our products.

Q. Have you talked to the board -- well, tell me, what do you remember about the times you attended board meetings and presented?

A. I can give you a couple examples.

Q. Sure.

A. As the head of regulatory, Purdue was looking at a biologic product, so that's a typical thing. The board was interested in what are the requirements for approval of a biologic product. So I gave a presentation regarding that. And the other one I remember well was -- or at least that I remember is related to buprenorphine development and the requirements.

Q. Do you remember any board meetings about addiction and abuse relating to

OxyContin?

A. The general topic or --

Q. Yes.

A. Not that I recall.

Q. Do you remember any board meeting at which you were brought in to discuss a safety issue relating to OxyContin?

A. I don't recall being in the meeting or -- no.

Q. What meeting are you referring to when you say "being in the meeting"?

A. So besides attending board meetings, I would prepare documents, regulatory portions, for instance, the head of R&D, who I would report to, was giving a presentation, and I would give portions. For instance, we're developing an abuse deterrent, the one I mentioned about IR, there was an advisory committee, and I presented what the plans were to address that, those kinds of things.

Q. Where if we wanted to give all of the meetings and documents that you prepared for presentation to the Purdue board, what's the easiest way to get -- to assemble that material?

A. Those -- the ones that I would produce I believe are on my computer.

Q. Do you know whether records are kept of the materials that are brought before the board of Purdue and its respective committees?

A. I don't know the handling of those documents.

(Document marked for identification as Exhibit Fanelli-23.)

BY MR. STEWART:

Q. I'd like to turn your attention to 23, which is a clipped group of documents. And Bates numbers appear to be contiguous. Could you turn -- well, first of all, could you read the front page of Exhibit 23. Tell me if you recognize it.

A. (Witness reviews document.) I recognize it, yes.

Q. What is it?

A. So this is dated -- hold on -- dated May 2015, part of preparing for any advisory committee, as part of that, the SOP we talked about yesterday, it's not really an SOP

but a planning document, there are practice sessions, and looking at this, I don't recall this specific document, but it says it's a draft briefing document in preparation of that meeting is what the author is saying.

Q. And turn the page to the page that's marked 4178.

A. Mm-hmm.

Q. Do you see that? Do you see that in this thread of e-mails is an e-mail that you wrote?

A. Mm-hmm.

Q. And do you see that you're talking about the preparation for the FDA advisory committee?

A. Yes.

Q. And what were you all preparing to do before the FDA advisory committee?

A. So all advisory committees have presentations by the sponsor, and that was what we were preparing -- I think, hold on a second. That's what we would be doing in a practice session, practice, sorry.

Q. And can you turn to the page

marked 4180.

A. Yes.

Q. And do you see that this is the cover page of the document that you're routing around entitled "Advisory Committee Briefing Materials"?

A. That's what it says, yes.

Q. And is this a draft of materials that ultimately would be provided to the FDA advisory committee?

A. That's what a draft briefing document -- there's requirements by sponsors to provide a briefing package to the committees, to the FDA.

Q. The point is you're pointing something together that ultimately would be given to the FDA advisory committee?

A. Yes, this is a draft of that piece.

Q. Okay. It's something that the company is going to use to communicate with the FDA?

A. Yes.

Q. And do you remember what the

advisory committee, the FDA advisory committee meeting on July 7th, 8th, 2015 was going to be discussing?

A. Yes, the reformulated OxyContin and this data related to it. As we discussed, that was related to a supplement we had submitted to add the category 4 data to the label, package insert.

Q. I take it when you present materials to an FDA advisory committee, you're attempting to present truthful and accurate materials?

A. Yes.

Q. Could you turn to page -- the page marked 4267.

A. It's in the second part. 4267?

Q. Yeah.

A. Okay.

Q. And do you see there's a number 12, and next to the number 12 on page that's marked 4267, there's a heading that says "Supportive Study 9: Changes in Doctor-Shopping Rates for OxyContin and Comparator Opioids"?

A. I see that, yes.

Q. Does that describe a study that Purdue conducted?

A. It was part of the package of studies, the data that were submitted at that time. Purdue conducted -- Purdue was involved in it. I'm not sure who conducted that study.

Q. Was it -- put it this way, is Purdue relying on the study in its presentation to the FDA?

A. We are showing these -- this is a -- I don't have the final document, but this is a draft of what was deemed might -- could end up in that document to FDA.

Q. Was there a final document that was submitted to the FDA for the advisory meeting that was held in 2015?

A. There was.

Q. So there was a final document, a final version of the document that we're looking at now produced to the FDA?

A. I believe there was.

Q. Okay. So if we wanted to know the final statement that Purdue made to the FDA, we'd want to look at that final version and see

if anything changed from this version, fair?

A. Yes.

Q. Okay. Summarizing this study, is this a study where Purdue is presenting information from the IMS, a prescription database, that calculates doctor shopping rates for particular products?

MR. SNAPP: Object to the form.

THE WITNESS: It's stated, again, these are -- there's many studies in here, some pivotal -- not pivotal -- some prime, some supportive, that at the time were under investigation.

This is -- the source is IMS database, and it's one of the studies that was ongoing.

BY MR. STEWART:

Q. Do you see on page 4268 the last paragraph on the page it says, "Product-specific doctor-shopping rates were estimated for each 6-month calendar interval. The prescriptions of a specific product, (e.g. OxyContin) for each patient were aligned by prescription start date and number of days supply."

Do you see that?

A. Yes.

Q. I mean, what this paragraph sets out is the methodology of a measurement of doctor shopping; is that fair?

A. Yes.

Q. And then could you turn to page 4271.

A. I'm sorry, 42?

Q. 71.

A. Yes.

Q. And do you see there's a graph on the top of 4271 entitled "Change in doctor-shopping rates for objection from pre-to-post-reformulation, by number of doctors and pharmacies with overlapping prescriptions"?

A. Yes, I see that.

Q. So what this study is showing here is a measurement of the change in doctor shopping that this study suggests occurred between the pre -- the time when you had preformulated OxyContin and then the post-reformulated OxyContin; is that fair?

A. Yes.

Q. Okay. Can you turn to page 4272. And do you see on page 4272 there's a heading 13 entitled "Supportive Study 10: Changes in OxyContin Diversion with Reformulation in the RADARS Drug Diversion Program"?

A. Yes.

Q. And do you see -- do you recall this study?

A. No, I do not.

Q. Okay. I take it if it's being reported to the FDA, then at least in the final version, you're going to have an accurate description of the study provided to the FDA advisory committee?

A. So, again, there are studies both within Purdue and across Purdue about doctor shopping. This is a draft, an accurate draft of the methodology that were conducted and at the time what the results were, if that's what you're asking.

Q. That's correct.

And do you see -- turn to page 4274. Do you see that there's a table 21 and it shows "Changes in Rates of Diversion After

Reformulation of OxyContin in the RADARS Drug Diversion Study"?

Do you see that?

A. Yes.

Q. And do you see at the top line it's got OxyContin and it shows the changing rates of diversion over time?

A. Yes.

Q. And while this is a draft report, I take it you'd agree that what Purdue presented to the FDA advisory committee is an analysis of changes in diversion over time of OxyContin, among other information?

MR. SNAPP: Object to the form.

THE WITNESS: So it never went to an advisory committee. What we were -- this would have been a briefing document to FDA, and as we talked earlier, that advisory committee was postponed.

BY MR. STEWART:

Q. It was submitted to the FDA, but, ultimately, the advisory committee itself didn't receive it is what you're saying?

A. Correct.

Q. Okay. I think we've covered this, but could you turn back to page 4272. Do you see there's a Section 13.2 Population that states, "individuals identified by law enforcement officers as engaging in diversion of prescription opioids. In the 4th quarter 2013, there were 219 participating agencies in 49 states covering 28% of the population."

Do you see that?

A. Yes.

Q. That's a description of the RADARS coverage?

A. Yes.

Q. Do you happen to know which state is not included?

A. I do not.

Q. Do you know whether Tennessee is the -- is included in the 49 states covered by RADARS?

A. I do not.

Q. Turn to page 4276, and do you see there's a paragraph 14 entitled "Supportive Study 11: OxyContin Prescribing Patterns Among Potentially High Risk Prescribers"?

A. Yes.
Q. Do you recall this study?
A. No, not in detail -- well, no. I know that there was a study related to ADD that was part of Paul's -- Dr. Coplan's write-up at the time. I don't remember the details.
Q. Do you remember that prescribing habits of doctors who had been identified as potentially involved in diversion were compared to the prescribing habits of doctors who had not been so identified by Purdue?
A. So we talked about that earlier. I was not -- I do not recall prior to today what the details were of that particular study.
Q. We'd have to look in the study to see the exact -- the best place to look to figure out what the details were or a good place would be in this report right here, fair?
MR. SNAPP: Object to the form.
THE WITNESS: This report is a draft description of that study, yes.
BY MR. STEWART:
Q. Right. You would find that a description of the study is reliable, assuming

it didn't change between this draft and the final report, fair?

A. The final briefing document, correct.

Q. We could look at that to see the population endpoint methods, results of the study and so forth, fair?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MR. STEWART:

Q. Do you know if Purdue ever conducted a study where they took these doctors that had been identified as potentially involved in diversion and compared their habits to other doctors and then used that as a means of determining other doctors that were probably involved in diversion?

A. I missed the --

Q. Sure. We just talked about a study where Purdue compared the prescribing habits of doctors that were potentially -- had been identified as potentially involved in diversion by Purdue and Purdue -- strike that. Let's get this clear.

We just talked about a study where Purdue took doctors in its Region 0 program that it had already identified as potentially involved in diversion and compared them to the broader population of prescribers; is that what we just talked about?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MR. STEWART:

Q. And there what Purdue is trying to suggest is that diversion among these doctors associated with diversion had gone down, fair?

MR. SNAPP: Object to the form.

THE WITNESS: We're showing the -- what happens to the prescriptions among those doctors after the reformulation. That's what we're showing.

BY MR. STEWART:

Q. So you've got these characteristics of doctors that Purdue suspects as being involved in diversion.

Do you know if Purdue ever looked at the other doctors in its population of

prescribers to find out which ones met the same criteria in terms of cash payments, high levels of prescribing, prescribing high dose OxyContin to find other doctors that potentially should be investigated for diversion?

MR. SNAPP: Object to form.

THE WITNESS: So we have that ADD program, it continues to be on, but I'm not aware of whether or not that particular study was done.

BY MR. STEWART:

Q. The ADD program, you're talking about the program that directs salespeople to report people in certain instances, correct?

A. Correct.

(Document marked for identification as Exhibit Fanelli-24.)

BY MR. STEWART:

Q. Turn to exhibit marked 24. Do you see that it's an e-mail and the Bates stamp number is -- ends in the number 2514?

A. I see that.

Q. And do you recognize this e-mail?

A. I need to look at it first.

(Witness reviews document.)

Q. And I'd suggest you look at the second page marked 2515.

A. (Witness reviews document.)

I looked at that.

Q. Do you see there's an e-mail and you're on it dated June 26, 2003?

A. Yes.

Q. Do you see it's entitled -- the subject is "professional associations and the potential FDA hearing"?

A. Yes.

Q. Do you see that the third paragraph outlines a series of organizations that Purdue is going to coordinate with in preparation for an FDA hearing?

MR. SNAPP: Object to the form.

THE WITNESS: That appears to be what that is, although I don't recall this e-mail.

BY MR. STEWART:

Q. Okay. And do you see at the bottom in paragraph marked 5 it says, "Pamela will work with Richard Fanelli who was

identified as the 'holder of the information' to ensure that he has all the names/contact information for those who have been contacted."

Do you see that?

A. I do.

Q. Is that a role you would typically play as kind of keep track of all of these organizations that were enlisted in the effort to communicate with the FDA?

MR. SNAPP: Object to the form.

THE WITNESS: No. My role, although I don't recall this, so, as I read it, my -- if there is an FDA meeting and we were communicating with FDA about such organizations, I would provide that communication to FDA.

BY MR. STEWART:

Q. Okay. So would you be interacting with groups like the American Academy of Family Practice, the American Pain Foundation and so forth?

A. Not at all.

Q. Who would do that?

A. Groups in our -- for instance,

Pam Bennett, I don't remember what group she was in, health professional, like under Dr. Haddox.

Q. Is it -- is it typical for Purdue when it's presented with an FDA hearing to coordinate with a whole bunch of allied groups, such as the groups listed, to enhance the communications before the agency?

MR. SNAPP: Object to the form.

THE WITNESS: It depends on what the purpose of the public meeting is.

BY MR. STEWART:

Q. So at times Purdue will reach out to allies and get them to come and participate as is being organized in this document that's before you?

MR. SNAPP: Object to the form.

THE WITNESS: Again, there are times when we would -- we have outside experts talking. It depends on what the -- for instance, in an advisory committee, Rick Dart from RADARS, you know, presented for us, those kinds of things. And I don't know what the -- I'm reading the title. I don't know

what the potential FDA was -- I don't recall this potential FDA hearing.

BY MR. STEWART:

Q. I notice the American Pain Foundation is one of the groups listed.

Is that a group that you've -- that Purdue, in your experience, has coordinated with more than once?

A. I don't know the details of our coordination with the American Pain Foundation.

Q. We'd have to talk to somebody in the group run by Dr. Haddox probably to figure out what sort of coordination was done?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not sure where that resides, we've had changes recently, but that type of function.

BY MR. STEWART:

Q. Dr. Haddox would head that up?

A. Had in the past, I'm not sure if he does today.

(Document marked for identification as Exhibit Fanelli-25.)

BY MR. STEWART:

Q. Turn to Exhibit 25.

Do you see it's an e-mail from Beth Conley to you and your response dated December 17th, 2009?

A. Yes.

Q. And do you see she's forwarding comments to a document "Providing Relief Preventing Abuse" brochure?

A. Yes.

Q. And she says, "Do you want to weigh in since nonbranded," and you say "nope."

A. Correct.

Q. And you didn't deal with nonbranded items?

MR. SNAPP: Object to the form.

THE WITNESS: I have dealt with nonbrand -- it depends on -- we talked earlier, different projects have different representations. I believe -- when did Beth -- I think Beth reported to me at this time. We talked earlier, as a supervisor, I might provide input. I don't recall why I said no. Was it

because Beth had already done it? I actually don't remember the details.

BY MR. STEWART:

Q. So it might have fallen within your area, you just don't know why, in this particular case, you didn't feel the need?

A. Correct.

Q. Okay. Let me ask you, could you turn to page 1609. Do you recognize the document Providing Relief Preventing Abuse?

A. I do not.

Q. Do you see it says "Provided as an educational service by Purdue"?

A. Where is that? Yeah, I see it on the left side there.

Q. Would that still be a nonbranded document if it has that indicator on it with the company logo?

A. Definition, it's in the SOP, but definition of brand, it's not exact, but includes when a -- one of our prescription drugs is mentioned in the piece.

Q. So the point is if it doesn't mention OxyContin by name, but merely talks

about pain and opioids, it would be nonbranded?

A. In general, yes.

Q. Turn to page 1607.

Do you have a Material Review Form like this for any document of this sort that the company is putting through the approval process?

A. Ask your question again.

Q. Well, do you see you have in front of you a Material Review Form?

A. Yes.

Q. Okay. What is the purpose of a Material Review Form?

A. So it's to -- now we do this electronically, but it has -- it gives identification of the products, who is going to use the products, the target audience, and then there's the individuals who review it with their determination of whether they sign off, for instance.

Q. Okay. And this is a way you can look at one of these forms and see who has looked at this document and what they've done; is that fair?

A. Yes, yes.
Q. So you see JDH down here has reviewed it, that's Haddox?
A. Dr. Haddox, yes, I see that.
Q. Question about the document itself, could you turn to page 1615?
A. Sorry, 16?
Q. 15.
A. 15.
Q. Do you see that?
A. Yes.
Q. Do you see there are all sorts of handwritten notes on the document?
A. I see that.
Q. Is this typical where people -- the people that review the document will mark it up, provide notes and develop the final language?
A. Correct.
Q. So any of these documents goes through this formal process?
A. Yes.
Q. Do you see where someone has put a bunch of Xs through the section that's

entitled "Pseudoaddiction"?

A. Yeah, I see that.

Q. Do you know why in 2009 someone was putting a bunch of Xs through pseudoaddiction?

A. I do not know.

Q. Okay. Are you familiar with the concept of pseudoaddiction?

A. Yes.

Q. Is it a scientifically recognized concept?

MR. SNAPP: Object to the form.

THE WITNESS: I don't have an answer for that.

BY MR. STEWART:

Q. Why not?

A. Pseudoaddiction is a -- was a description of -- I think we talked about that earlier too, of pharmacological and responses to medicines, and it's -- I don't believe it's being used today.

Q. All right. I mean, it's something that Dr. Haddox came up with, right; he's the father of that concept?

MR. SNAPP: Object to the form.
THE WITNESS: I'm not aware of that.
BY MR. STEWART:
Q. As far as you know, as head of regulatory affairs for Purdue, there's never been an actual scientific study supporting the concept of pseudoaddiction, right?
MR. SNAPP: Object to the form.
THE WITNESS: I'm not aware of whether or not there has been one.
BY MR. STEWART:
Q. You couldn't name one today, as we're sitting here?
A. That's correct.
Q. And you're not aware, to make it clear, that there has been such a study?
A. Correct.
Q. Could you turn to Exhibit 53, which I think your counsel has pulled out of the pile.
A. I have 53 here.
Q. We looked at this before.
Could you turn to page 106?

MR. SNAPP: I'm sorry, could we wait one second. Just had to check his insulin pump.

THE WITNESS: No problem, I did. So if we don't finish in the next 15 minutes or so.

MR. STEWART: We're going to finish in the next two minutes.

THE WITNESS: Okay. Sorry, so where?

BY MR. STEWART:

Q. Turn to page that's marked Bates number 3106.

Do you see this is one of a number of pages in this document that lists a study?

A. Yes.

Q. And this document, the overall exhibit, is your routing letter and a study that purports to gather and summarize a series of studies on a particular topic, fair?

A. It's a review of those, yes.

Q. And I take it if a study is not viewed as at least scientific, part of the

scientific inquiry, you wouldn't list it?

A. I wouldn't characterize it that way, so this --

Q. How would you characterize it?

A. This is a review of the literature in order to, you know, provide information related to the topic. If you're going to do a complete literature review would include all the publications -- could include all the publications with the description of the limitations, plus and minuses. So I'm not aware, and I'd have to read it more carefully to understand, is this a complete literature description or did they select and so forth.

Q. We'd have to look at the document that would describe --

A. Yes.

Q. -- how that worked?

Here's a question, turn to page 3121.

A. Got it.

Q. Do you see that on the last -- in the first section numbered 5.1.1, if you look at the last -- second to last sentence it says,

"Two studies highlighted below used randomized patient populations and higher quality design and methodologies compared to the other published studies."

Do you see that?

A. Yes.

Q. And so I think would you agree it's referring to study 1, Adams and study 2, Naliboff?

A. Yes.

Q. Okay. Are you familiar with the Adams study?

A. No, I am not.

Q. Do you know who Adams is?

A. No.

Q. If I wanted to know whether the authors of the Adams study had received money from Purdue, how would I do that?

A. I'm not aware -- there's the Sunshine Act where, although it would depend on if that person was a prescriber, so I'm not aware of the details of how to find that out.

Q. Who at Purdue would have -- would be the person to ask whether the author of a

particular study was on Purdue's payroll or had received money or something of value from Purdue?

MR. SNAPP: Object to the form.

THE WITNESS: That would be our compliance department.

BY MR. STEWART:

Q. What human being today?

MR. SNAPP: Object to the form.

THE WITNESS: Maggie Feltz is the head of that group.

MR. STEWART: I've got nothing further. Thank you.

THE VIDEOGRAPHER: Off the record?

BY MR. SNAPP:

Q. Dr. Fanelli, I just have a few follow-up questions.

First of all, I just wanted to clarify, I'm handing you what's been marked as Deposition Exhibit 2, and I just want to clarify for the record, does that Exhibit 2, which is your CV, and I think you testified it's your current CV, does it include your current

position?

A. No, it does not. I don't know if I've updated it, but the only thing that's not on here is my appointment in 2014 as the head of regulatory affairs.

Q. Thank you.

You were asked some questions by counsel earlier this afternoon about Purdue Pharma and Rhodes Pharma, and you gave some testimony about the boards of directors.

Do you know, sitting here today, who is on the boards of directors of Rhodes and Purdue Pharma?

A. I do not know the list.

MR. SNAPP: I have no further questions.

MR. CRUEGER: Nothing here.

MR. SNAPP: Off the record.

THE VIDEOGRAPHER: Stand by.

Okay. The time is 5:23 p.m., going off the record.

(Witness excused.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I, RICHARD J. FANELLI, Ph.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

RICHARD J. FANELLI, Ph.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2018.

My commission expires:_____

_____

Notary Public